



Clinical trial results:

A phase I/II open-label, dose escalation study to investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of GSK525762 in subjects with relapsed, refractory hematologic malignancies

Summary

EudraCT number	2013-000445-39
Trial protocol	GB ES
Global end of trial date	30 April 2020

Results information

Result version number	v1 (current)
This version publication date	12 May 2021
First version publication date	12 May 2021

Trial information

Trial identification

Sponsor protocol code	116183
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom, TW8 9GS
Public contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 October 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 April 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

PART 1: To determine the safety, tolerability and maximum tolerated dose (MTD), following once daily (QD) and/or twice daily (BID) dosing schedules, establishing the recommended Phase 2 dose (RP2D) of GSK525762 in adult subjects with acute leukemia (AML), multiple myeloma (MM), or non-Hodgkin's lymphoma (NHL).

PART 2: To evaluate clinical efficacy after treatment with GSK525762 in AML. To evaluate clinical efficacy after treatment with GSK525762 in MM.

To evaluate clinical efficacy after treatment with GSK525762 in NHL.

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 May 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 27
Country: Number of subjects enrolled	Spain: 22
Country: Number of subjects enrolled	United Kingdom: 12
Country: Number of subjects enrolled	Korea, Republic of: 8
Country: Number of subjects enrolled	United States: 42
Worldwide total number of subjects	111
EEA total number of subjects	22

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	51
From 65 to 84 years	58
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

This was an open-label repeat dose, multicenter study to investigate the safety, pharmacokinetics (PK), pharmacodynamics and clinical activity of GSK525762 in participants with relapsed, refractory hematologic malignancies. The study was conducted in 2 parts: Part 1 (dose escalation) and Part 2 (dose expansion)

Pre-assignment

Screening details:

A total of 111 participants were enrolled (87 participants in Part 1 and 24 participants in Part 2) across the study centers in Australia, Spain, Great Britain, South Korea and United State of America (USA).

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1: GSK525762 5 mg QD

Arm description:

Participants were administered once daily oral dose of 5 milligrams (mg) GSK525762.

Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Arm title	Part 1: GSK525762 10 mg QD
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Arm description:

Participants were administered once daily oral dose of 10 mg GSK525762.

Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Arm title	Part 1: GSK525762 20 mg QD
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Arm description:

Participants were administered once daily oral dose of 20 mg GSK525762.

Arm type	Experimental
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Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received an oral dose of GSK525762 once daily.	
Arm title	Part 1: GSK525762 30 mg QD MM
Arm description:	
Participants with multiple myeloma (MM) were administered once daily oral dose of 30 mg GSK525762.	
Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received an oral dose of GSK525762 once daily.	
Arm title	Part 1: GSK525762 40 mg QD
Arm description:	
Participants were administered once daily oral dose of 40 mg GSK525762.	
Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received an oral dose of GSK525762 once daily.	
Arm title	Part 1: GSK525762 40 mg QD MM
Arm description:	
Participants with MM were administered once daily oral dose of 40 mg GSK525762.	
Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received an oral dose of GSK525762 once daily.	
Arm title	Part 1: GSK525762 60 mg QD AML
Arm description:	
Participants with Acute Myeloid Leukemia (AML) were administered once daily oral dose of 60 mg GSK525762.	
Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Arm title	Part 1: GSK525762 60 mg QD NHL
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Arm description:

Participants with Non-Hodgkin's Lymphoma (NHL) were administered once daily oral dose of 60 mg GSK525762.

Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Arm title	Part 1: GSK525762 60 mg QD MM
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Arm description:

Participants with MM were administered once daily oral dose of 60 mg GSK525762.

Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Arm title	Part 1: GSK525762 75 mg QD AML
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Arm description:

Participants with AML were administered once daily oral dose of 75 mg GSK525762.

Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Arm title	Part 1: GSK525762 80 mg QD
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Arm description:

Participants were administered once daily oral dose of 80 mg GSK525762.

Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Arm title	Part 1: GSK525762 80 mg QD AML
Arm description: Participants with AML were administered once daily oral dose of 80 mg GSK525762.	
Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Participants received an oral dose of GSK525762 once daily.	
Arm title	Part 1: GSK525762 80 mg QD NHL
Arm description: Participants with NHL were administered once daily oral dose of 80 mg GSK525762.	
Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Participants received an oral dose of GSK525762 once daily.	
Arm title	Part 1: GSK525762 100 mg QD AML
Arm description: Participants with AML were administered once daily oral dose of 100 mg GSK525762.	
Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Participants received an oral dose of GSK525762 once daily.	
Arm title	Part 1: GSK525762 120 mg QD AML
Arm description: Participants with AML were administered once daily oral dose of 120 mg GSK525762.	
Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Participants received an oral dose of GSK525762 once daily.	
Arm title	Part 2: GSK525762 60 mg QD CTCL
Arm description: Participants Cutaneous T cell lymphoma (CTCL) were administered once daily oral dose of 60 mg GSK525762.	
Arm type	Experimental

Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Arm title	Part 2: GSK525762 75 mg QD MDS
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Arm description:

Participants with Myelodysplastic Syndrome (MDS) were administered once daily oral dose of 75 mg GSK525762.

Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Arm title	Part 2: GSK525762 80 mg QD CTCL
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Arm description:

Participants CTCL were administered once daily oral dose of 80 mg GSK525762

Arm type	Experimental
Investigational medicinal product name	GSK525762
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received an oral dose of GSK525762 once daily.

Number of subjects in period 1	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD
Started	1	1	1
Completed	1	1	1
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Other Study closed/terminated	-	-	-
Lost to follow-up	-	-	-
Investigator discretion	-	-	-

Number of subjects in period 1	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM
Started	5	1	4
Completed	4	0	4
Not completed	1	1	0
Consent withdrawn by subject	1	-	-

Other Study closed/terminated	-	-	-
Lost to follow-up	-	1	-
Investigator discretion	-	-	-

Number of subjects in period 1	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Started	8	18	3
Completed	7	16	2
Not completed	1	2	1
Consent withdrawn by subject	1	1	1
Other Study closed/terminated	-	-	-
Lost to follow-up	-	1	-
Investigator discretion	-	-	-

Number of subjects in period 1	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Started	8	1	7
Completed	8	1	7
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Other Study closed/terminated	-	-	-
Lost to follow-up	-	-	-
Investigator discretion	-	-	-

Number of subjects in period 1	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML
Started	7	16	6
Completed	7	15	6
Not completed	0	1	0
Consent withdrawn by subject	-	-	-
Other Study closed/terminated	-	-	-
Lost to follow-up	-	-	-
Investigator discretion	-	1	-

Number of subjects in period 1	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL
Started	7	16	1
Completed	1	13	0
Not completed	6	3	1
Consent withdrawn by subject	2	-	-
Other Study closed/terminated	4	3	1
Lost to follow-up	-	-	-
Investigator discretion	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	Part 1: GSK525762 5 mg QD
Reporting group description: Participants were administered once daily oral dose of 5 milligrams (mg) GSK525762.	
Reporting group title	Part 1: GSK525762 10 mg QD
Reporting group description: Participants were administered once daily oral dose of 10 mg GSK525762.	
Reporting group title	Part 1: GSK525762 20 mg QD
Reporting group description: Participants were administered once daily oral dose of 20 mg GSK525762.	
Reporting group title	Part 1: GSK525762 30 mg QD MM
Reporting group description: Participants with multiple myeloma (MM) were administered once daily oral dose of 30 mg GSK525762.	
Reporting group title	Part 1: GSK525762 40 mg QD
Reporting group description: Participants were administered once daily oral dose of 40 mg GSK525762.	
Reporting group title	Part 1: GSK525762 40 mg QD MM
Reporting group description: Participants with MM were administered once daily oral dose of 40 mg GSK525762.	
Reporting group title	Part 1: GSK525762 60 mg QD AML
Reporting group description: Participants with Acute Myeloid Leukemia (AML) were administered once daily oral dose of 60 mg GSK525762.	
Reporting group title	Part 1: GSK525762 60 mg QD NHL
Reporting group description: Participants with Non-Hodgkin's Lymphoma (NHL) were administered once daily oral dose of 60 mg GSK525762.	
Reporting group title	Part 1: GSK525762 60 mg QD MM
Reporting group description: Participants with MM were administered once daily oral dose of 60 mg GSK525762.	
Reporting group title	Part 1: GSK525762 75 mg QD AML
Reporting group description: Participants with AML were administered once daily oral dose of 75 mg GSK525762.	
Reporting group title	Part 1: GSK525762 80 mg QD
Reporting group description: Participants were administered once daily oral dose of 80 mg GSK525762.	
Reporting group title	Part 1: GSK525762 80 mg QD AML
Reporting group description: Participants with AML were administered once daily oral dose of 80 mg GSK525762.	
Reporting group title	Part 1: GSK525762 80 mg QD NHL
Reporting group description: Participants with NHL were administered once daily oral dose of 80 mg GSK525762.	
Reporting group title	Part 1: GSK525762 100 mg QD AML
Reporting group description: Participants with AML were administered once daily oral dose of 100 mg GSK525762.	
Reporting group title	Part 1: GSK525762 120 mg QD AML
Reporting group description: Participants with AML were administered once daily oral dose of 120 mg GSK525762.	
Reporting group title	Part 2: GSK525762 60 mg QD CTCL

Reporting group description:

Participants Cutaneous T cell lymphoma (CTCL) were administered once daily oral dose of 60 mg GSK525762.

Reporting group title	Part 2: GSK525762 75 mg QD MDS
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Reporting group description:

Participants with Myelodysplastic Syndrome (MDS) were administered once daily oral dose of 75 mg GSK525762.

Reporting group title	Part 2: GSK525762 80 mg QD CTCL
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Reporting group description:

Participants CTCL were administered once daily oral dose of 80 mg GSK525762

Reporting group values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD
Number of subjects	1	1	1
Age categorical Units: Subjects			
18-64 years	1	0	0
65-74 years	0	1	0
>74 years	0	0	1
Sex: Female, Male Units: Participants			
Female	0	0	0
Male	0	0	0
Data not reported due to confidentiality/ privacy	1	1	1
Race/Ethnicity, Customized Units: Subjects			
Japanese (H)/eastAsian(H) /Southeast Asian(H)	0	0	0
Black or African american	0	0	0
Native hawaiian or other pacific islander	0	0	0
White	0	0	0
Asian & native hawaiian/other pacific islander	0	0	0
Missing	0	0	0
Data not reported due to confidentiality/ privacy	1	1	1

Reporting group values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM
Number of subjects	5	1	4
Age categorical Units: Subjects			
18-64 years	4	0	3
65-74 years	0	1	0
>74 years	1	0	1
Sex: Female, Male Units: Participants			
Female	2	0	2
Male	3	0	2
Data not reported due to confidentiality/ privacy	0	1	0

Race/Ethnicity, Customized			
Units: Subjects			
Japanese (H)/eastAsian(H) /Southeast Asian(H)	2	0	0
Black or African american	0	0	0
Native hawaiian or other pacific islander	0	0	0
White	3	0	4
Asian & native hawaiian/other pacific islander	0	0	0
Missing	0	0	0
Data not reported due to confidentiality/ privacy	0	1	0

Reporting group values	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Number of subjects	8	18	3
Age categorical			
Units: Subjects			
18-64 years	3	11	3
65-74 years	5	5	0
>74 years	0	2	0
Sex: Female, Male			
Units: Participants			
Female	1	5	1
Male	7	13	2
Data not reported due to confidentiality/ privacy	0	0	0
Race/Ethnicity, Customized			
Units: Subjects			
Japanese (H)/eastAsian(H) /Southeast Asian(H)	0	5	1
Black or African american	0	1	1
Native hawaiian or other pacific islander	0	0	0
White	6	12	1
Asian & native hawaiian/other pacific islander	0	0	0
Missing	2	0	0
Data not reported due to confidentiality/ privacy	0	0	0

Reporting group values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Number of subjects	8	1	7
Age categorical			
Units: Subjects			
18-64 years	3	0	3
65-74 years	3	0	2
>74 years	2	1	2
Sex: Female, Male			
Units: Participants			
Female	7	0	4
Male	1	0	3
Data not reported due to confidentiality/ privacy	0	1	0

Race/Ethnicity, Customized Units: Subjects			
Japanese (H)/eastAsian(H) /Southeast Asian(H)	0	0	0
Black or African american	0	0	2
Native hawaiian or other pacific islander	0	0	0
White	8	0	5
Asian & native hawaiian/other pacific islander	0	0	0
Missing	0	0	0
Data not reported due to confidentiality/ privacy	0	1	0

Reporting group values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML
Number of subjects	7	16	6
Age categorical Units: Subjects			
18-64 years	4	7	4
65-74 years	3	3	1
>74 years	0	6	1
Sex: Female, Male Units: Participants			
Female	2	6	1
Male	5	10	5
Data not reported due to confidentiality/ privacy	0	0	0
Race/Ethnicity, Customized Units: Subjects			
Japanese (H)/eastAsian(H) /Southeast Asian(H)	1	1	0
Black or African american	0	0	0
Native hawaiian or other pacific islander	1	0	0
White	5	14	6
Asian & native hawaiian/other pacific islander	0	0	0
Missing	0	1	0
Data not reported due to confidentiality/ privacy	0	0	0

Reporting group values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL
Number of subjects	7	16	1
Age categorical Units: Subjects			
18-64 years	4	1	0
65-74 years	2	9	1
>74 years	1	6	0
Sex: Female, Male Units: Participants			
Female	5	6	0
Male	2	10	0
Data not reported due to confidentiality/ privacy	0	0	1

Race/Ethnicity, Customized Units: Subjects			
Japanese (H)/eastAsian(H) /Southeast Asian(H)	1	0	0
Black or African american	0	1	0
Native hawaiian or other pacific islander	0	0	0
White	5	15	0
Asian & native hawaiian/other pacific islander	0	0	0
Missing	1	0	0
Data not reported due to confidentiality/ privacy	0	0	1

Reporting group values	Total		
Number of subjects	111		
Age categorical Units: Subjects			
18-64 years	51		
65-74 years	36		
>74 years	24		
Sex: Female, Male Units: Participants			
Female	42		
Male	63		
Data not reported due to confidentiality/ privacy	6		
Race/Ethnicity, Customized Units: Subjects			
Japanese (H)/eastAsian(H) /Southeast Asian(H)	11		
Black or African american	5		
Native hawaiian or other pacific islander	1		
White	84		
Asian & native hawaiian/other pacific islander	0		
Missing	4		
Data not reported due to confidentiality/ privacy	6		

End points

End points reporting groups

Reporting group title	Part 1: GSK525762 5 mg QD
Reporting group description: Participants were administered once daily oral dose of 5 milligrams (mg) GSK525762.	
Reporting group title	Part 1: GSK525762 10 mg QD
Reporting group description: Participants were administered once daily oral dose of 10 mg GSK525762.	
Reporting group title	Part 1: GSK525762 20 mg QD
Reporting group description: Participants were administered once daily oral dose of 20 mg GSK525762.	
Reporting group title	Part 1: GSK525762 30 mg QD MM
Reporting group description: Participants with multiple myeloma (MM) were administered once daily oral dose of 30 mg GSK525762.	
Reporting group title	Part 1: GSK525762 40 mg QD
Reporting group description: Participants were administered once daily oral dose of 40 mg GSK525762.	
Reporting group title	Part 1: GSK525762 40 mg QD MM
Reporting group description: Participants with MM were administered once daily oral dose of 40 mg GSK525762.	
Reporting group title	Part 1: GSK525762 60 mg QD AML
Reporting group description: Participants with Acute Myeloid Leukemia (AML) were administered once daily oral dose of 60 mg GSK525762.	
Reporting group title	Part 1: GSK525762 60 mg QD NHL
Reporting group description: Participants with Non-Hodgkin's Lymphoma (NHL) were administered once daily oral dose of 60 mg GSK525762.	
Reporting group title	Part 1: GSK525762 60 mg QD MM
Reporting group description: Participants with MM were administered once daily oral dose of 60 mg GSK525762.	
Reporting group title	Part 1: GSK525762 75 mg QD AML
Reporting group description: Participants with AML were administered once daily oral dose of 75 mg GSK525762.	
Reporting group title	Part 1: GSK525762 80 mg QD
Reporting group description: Participants were administered once daily oral dose of 80 mg GSK525762.	
Reporting group title	Part 1: GSK525762 80 mg QD AML
Reporting group description: Participants with AML were administered once daily oral dose of 80 mg GSK525762.	
Reporting group title	Part 1: GSK525762 80 mg QD NHL
Reporting group description: Participants with NHL were administered once daily oral dose of 80 mg GSK525762.	
Reporting group title	Part 1: GSK525762 100 mg QD AML
Reporting group description: Participants with AML were administered once daily oral dose of 100 mg GSK525762.	
Reporting group title	Part 1: GSK525762 120 mg QD AML
Reporting group description: Participants with AML were administered once daily oral dose of 120 mg GSK525762.	
Reporting group title	Part 2: GSK525762 60 mg QD CTCL

Reporting group description:

Participants Cutaneous T cell lymphoma (CTCL) were administered once daily oral dose of 60 mg GSK525762.

Reporting group title	Part 2: GSK525762 75 mg QD MDS
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Reporting group description:

Participants with Myelodysplastic Syndrome (MDS) were administered once daily oral dose of 75 mg GSK525762.

Reporting group title	Part 2: GSK525762 80 mg QD CTCL
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Reporting group description:

Participants CTCL were administered once daily oral dose of 80 mg GSK525762

Subject analysis set title	Part 2: GSK525762 75 mg QD MDS
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Participants with Myelodysplastic Syndrome (MDS) were administered once daily oral dose of 75 mg GSK525762.

Primary: Part 1: Number of participants with non-serious adverse events (AEs) and serious adverse events (SAEs) and AE leading to discontinuation (AELD)

End point title	Part 1: Number of participants with non-serious adverse events (AEs) and serious adverse events (SAEs) and AE leading to discontinuation (AELD) ^{[1][2]}
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End point description:

An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and SAE is defined as any untoward medical occurrence that, at any dose which results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or, is a congenital anomaly/birth defect. AELD is adverse events leading to permanent discontinuation of study treatment. All Treated Population consists of all participants that received at least one dose of study treatment.

End point type	Primary
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End point timeframe:

Up to 86.9 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[3]	1 ^[4]	1 ^[5]	5 ^[6]
Units: Participants				
Non-serious AEs	1	1	1	5
SAEs	1	0	0	4
AELD	0	0	0	1

Notes:

[3] - All Treated Population

[4] - All Treated Population

[5] - All Treated Population

[6] - All Treated Population

End point values	Part 1:	Part 1:	Part 1:	Part 1:
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	GSK525762 40 mg QD	GSK525762 40 mg QD MM	GSK525762 60 mg QD AML	GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[7]	4 ^[8]	8 ^[9]	18 ^[10]
Units: Participants				
Non-serious AEs	1	4	8	18
SAEs	0	3	6	12
AELD	0	1	3	3

Notes:

[7] - All Treated Population

[8] - All Treated Population

[9] - All Treated Population

[10] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[11]	8 ^[12]	1 ^[13]	7 ^[14]
Units: Participants				
Non-serious AEs	3	8	1	7
SAEs	2	8	1	6
AELD	0	2	0	3

Notes:

[11] - All Treated Population

[12] - All Treated Population

[13] - All Treated Population

[14] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[15]	16 ^[16]	6 ^[17]	
Units: Participants				
Non-serious AEs	7	16	6	
SAEs	7	14	6	
AELD	1	8	2	

Notes:

[15] - All Treated Population

[16] - All Treated Population

[17] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of participants with Dose Limiting Toxicities (DLTs)

End point title	Part 1: Number of participants with Dose Limiting Toxicities (DLTs) ^{[18][19]}
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End point description:

An event was considered DLT if it occurred within first 3weeks of treatment & met one of following criteria:unless it was clearly established that event is unrelated to treatment:Grade4 neutropenia persisting for >=7 days/febrile neutropenia not responding to treatment within 24hours, Grade4

thrombocytopenia lasting more than 7day & not responding to transfusions/Grade3 thrombocytopenia associated with bleeding (>10milliliter [mL]), Drug-related Grade 3/4 non-hematologic toxicity as described in National Cancer Institute-Common Terminology Criteria for Adverse Events(NCI-CTCAE)version 4.0, Drug-related Grade2 non-hematological toxicity, Grade2 Troponin T elevation(central laboratory>Upper Limit of Normal[ULN]),measured on two separate occasions within 48 hours, Treatment delay of 14 days/greater due to unresolved drug-related toxicity,ALT>=3xULN+bilirubin>=2xULN(>35% direct)/Alanine aminotransferase(ALT) between 3-5xULN with bilirubin<2xULN but with hepatitis symptom/rash/ALT>=5xULN.

End point type	Primary
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End point timeframe:

Up to 3 weeks

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[20]	1 ^[21]	1 ^[22]	5 ^[23]
Units: Participants	0	0	0	0

Notes:

[20] - All Treated Population

[21] - All Treated Population

[22] - All Treated Population

[23] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[24]	4 ^[25]	8 ^[26]	18 ^[27]
Units: Participants	0	0	0	2

Notes:

[24] - All Treated Population

[25] - All Treated Population

[26] - All Treated Population

[27] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[28]	8 ^[29]	1 ^[30]	7 ^[31]
Units: Participants	0	0	0	0

Notes:

[28] - All Treated Population

[29] - All Treated Population

[30] - All Treated Population

[31] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[32]	16 ^[33]	6 ^[34]	
Units: Participants	0	0	1	

Notes:

[32] - All Treated Population

[33] - All Treated Population

[34] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of participants with dose reductions

End point title	Part 1: Number of participants with dose reductions ^{[35][36]}
End point description:	Number of participants with dose reductions due to any reason is presented.
End point type	Primary
End point timeframe:	Up to 86.9 weeks

Notes:

[35] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[37]	1 ^[38]	1 ^[39]	5 ^[40]
Units: Participants	0	0	0	0

Notes:

[37] - All Treated Population

[38] - All Treated Population

[39] - All Treated Population

[40] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[41]	4 ^[42]	8 ^[43]	18 ^[44]
Units: Participants	0	1	0	8

Notes:

[41] - All Treated Population

[42] - All Treated Population

[43] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[45]	8 ^[46]	1 ^[47]	7 ^[48]
Units: Participants	0	1	0	0

Notes:

[45] - All Treated Population

[46] - All Treated Population

[47] - All Treated Population

[48] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[49]	16 ^[50]	6 ^[51]	
Units: Participants	5	3	1	

Notes:

[49] - All Treated Population

[50] - All Treated Population

[51] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of participants with any dose interruptions or delays

End point title	Part 1: Number of participants with any dose interruptions or delays ^[52] ^[53]
End point description: Number of participants with any dose interruptions/ delays is presented.	
End point type	Primary
End point timeframe: Up to 86.9 weeks	

Notes:

[52] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[54]	1 ^[55]	1 ^[56]	5 ^[57]
Units: Participants	1	0	1	3

Notes:

[54] - All Treated Population

[55] - All Treated Population

[56] - All Treated Population

[57] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[58]	4 ^[59]	8 ^[60]	18 ^[61]
Units: Participants	0	3	5	15

Notes:

[58] - All Treated Population

[59] - All Treated Population

[60] - All Treated Population

[61] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[62]	8 ^[63]	1 ^[64]	7 ^[65]
Units: Participants	2	7	1	6

Notes:

[62] - All Treated Population

[63] - All Treated Population

[64] - All Treated Population

[65] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[66]	16 ^[67]	6 ^[68]	
Units: Participants	7	13	6	

Notes:

[66] - All Treated Population

[67] - All Treated Population

[68] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of participants with grade change from Baseline in clinical chemistry parameters

End point title	Part 1: Number of participants with grade change from
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End point description:

Blood samples were collected for analysis of following clinical chemistry parameters: glucose, Pro. INR, albumin, amylase, alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, calcium, calcium ionized, cholesterol, creatinine, creatine kinase, lipase, potassium, magnesium, sodium, triglycerides, alkaline phosphatase (ALP). Laboratory parameters were graded according to NCI-CTCAE version 4.0. Grade 1: mild; Grade 2: moderate; Grade 3: severe/medically significant; Grade 4: life-threatening consequences; Grade 5: death related to AE. Higher grade indicates greater severity. An increase was defined as increase relative to Baseline. Baseline was most recent, non-missing value prior to/on first study treatment dose date. Data for worst-case post Baseline with any grade increase is presented. Only those participants with data available at specified data points were analyzed (represented by n=X in category titles). 77777 indicates data is not

End point type	Primary
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End point timeframe:

Up to 86.9 weeks

Notes:

[69] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[71]	1 ^[72]	1 ^[73]	5 ^[74]
Units: Participants				
Glucose, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	0	1	3
Pro.INR, n=0,1,1,5,1,3,4,16,3,4,0,6,5,11,4	77777	0	1	3
Albumin, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	0	1	1
ALT, n=1,1,1,5,1,4,8,18,3,8,1,7,7,15,6	0	0	0	1
Amylase, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,5	0	1	0	1
AST, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	0	0	1	1
Bilirubin, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	1	0	1	0
Calcium, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	0	0	0	2
Calcium Ionized, n=1,1,1,4,1,4,7,17,3,8,1,7,7,15,6	1	0	1	1
Cholesterol, n=1,1,1,4,1,4,3,17,3,6,1,7, 6,10,3	0	0	1	1
Creatine Kinase, n=1,1,1,2,1,4,8,18,3,7,1,7,7,16,6	0	0	0	1
Creatinine, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	0	0	0	1
Lipase, n=1,1,1,5,1,4,6,18,3,8,1,7,6,15,6	0	0	0	0
Potassium, n=1,1,1,5,1,4,7,18,3,8,1,7,6,16,6	1	0	1	1
Magnesium, n=1,1,1,5,1,4,7,18,3,8,1,7, 7,16,6	1	0	0	1
Sodium, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	0	0	3

Triglycerides, n=1,1,1,4,1,4,3,17,3,6,1,7,6,10,3	1	0	1	2
ALP, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	0	0	0	1

Notes:

[71] - All Treated Population

[72] - All Treated Population

[73] - All Treated Population

[74] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[75]	4 ^[76]	8 ^[77]	18 ^[78]
Units: Participants				
Glucose, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	3	6	16
Pro.INR, n=0,1,1,5,1,3,4,16,3,4,0,6,5,11,4	0	1	3	10
Albumin, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	0	4	7
ALT, n=1,1,1,5,1,4,8,18,3,8,1,7,7,15,6	0	1	1	4
Amylase, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,5	1	0	0	5
AST, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	0	0	1	5
Bilirubin, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	1	1	6	8
Calcium, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	0	1	5	6
Calcium Ionized, n=1,1,1,4,1,4,7,17,3,8,1,7,7,15,6	1	3	1	2
Cholesterol, n=1,1,1,4,1,4,3,17,3,6,1,7,6,10,3	0	1	0	1
Creatine Kinase, n=1,1,1,2,1,4,8,18,3,7,1,7,7,16,6	0	1	2	3
Creatinine, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	0	1	4	5
Lipase, n=1,1,1,5,1,4,6,18,3,8,1,7,6,15,6	1	1	0	5
Potassium, n=1,1,1,5,1,4,7,18,3,8,1,7,6,16,6	0	3	3	4
Magnesium, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	2	3	4
Sodium, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	3	3	6
Triglycerides, n=1,1,1,4,1,4,3,17,3,6,1,7,6,10,3	1	2	1	4
ALP, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	0	2	0	2

Notes:

[75] - All Treated Population

[76] - All Treated Population

[77] - All Treated Population

[78] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[79]	8 ^[80]	1 ^[81]	7 ^[82]
Units: Participants				
Glucose, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	2	8	1	6
Pro.INR, n=0,1,1,5,1,3,4,16,3,4,0,6,5,11,4	1	3	77777	4
Albumin, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	3	1	3
ALT, n=1,1,1,5,1,4,8,18,3,8,1,7,7,15,6	1	1	0	1
Amylase, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,5	2	0	0	3
AST, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	1	0	0	3
Bilirubin, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	1	7	1	6
Calcium, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	0	5	0	4
Calcium Ionized, n=1,1,1,4,1,4,7,17,3,8,1,7,7,15,6	0	3	0	3
Cholesterol,n=1,1,1,4,1,4,3,17,3,6,1,7,6,10,3	1	1	1	2
Creatine Kinase, n=1,1,1,2,1,4,8,18,3,7,1,7,7,16,6	1	0	0	1
Creatinine, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	1	0	3
Lipase, n=1,1,1,5,1,4,6,18,3,8,1,7,6,15,6	0	2	0	2
Potassium, n=1,1,1,5,1,4,7,18,3,8,1,7,6,16,6	2	5	1	5
Magnesium,n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	2	1	1	4
Sodium, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	4	1	4
Triglycerides, n=1,1,1,4,1,4,3,17,3,6,1,7,6,10,3	1	3	1	5
ALP, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	1	0	1	4

Notes:

[79] - All Treated Population

[80] - All Treated Population

[81] - All Treated Population

[82] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[83]	16 ^[84]	6 ^[85]	
Units: Participants				
Glucose, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	6	15	3	
Pro.INR, n=0,1,1,5,1,3,4,16,3,4,0,6,5,11,4	5	8	3	
Albumin, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	3	6	1	
ALT, n=1,1,1,5,1,4,8,18,3,8,1,7,7,15,6	3	4	0	
Amylase, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,5	4	3	0	
AST, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	3	4	1	

Bilirubin, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	5	12	4	
Calcium, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	6	5	
Calcium Ionized, n=1,1,1,4,1,4,7,17,3,8,1,7,7,15,6	3	6	2	
Cholesterol,n=1,1,1,4,1,4,3,17,3,6,1,7, 6,10,3	2	3	0	
Creatine Kinase, n=1,1,1,2,1,4,8,18,3,7,1,7,7,16,6	2	4	0	
Creatinine, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	2	6	1	
Lipase, n=1,1,1,5,1,4,6,18,3,8,1,7,6,15,6	3	0	1	
Potassium, n=1,1,1,5,1,4,7,18,3,8,1,7,6,16,6	4	7	3	
Magnesium,n=1,1,1,5,1,4,7,18,3,8,1,7, 7,16,6	5	8	2	
Sodium, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	2	9	3	
Triglycerides, n=1,1,1,4,1,4,3,17,3,6,1,7,6,10,3	2	8	2	
ALP, n=1,1,1,5,1,4,8,18,3,8,1,7,7,16,6	3	1	1	

Notes:

[83] - All Treated Population

[84] - All Treated Population

[85] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of participants with grade change from Baseline in hematology parameters

End point title	Part 1: Number of participants with grade change from Baseline in hematology parameters ^{[86][87]}
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End point description:

Blood samples were collected for analysis of following hematology parameters: hemoglobin, lymphocytes, neutrophils, platelets & leukocytes. The laboratory parameters were graded according to NCI-CTCAE version 4.0. Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; Grade 4: life-threatening consequences; Grade 5: death related to AE. Higher grade indicates greater severity. An increase is defined as an increase in CTCAE grade relative to Baseline grade. Baseline was most recent, non-missing value prior to or on the first study treatment dose date. Data for worst-case post Baseline with any grade increase is presented. Only those participants with data available at specified data points were analyzed (represented by n=X in category titles).77777 indicates data is not available.

End point type	Primary
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End point timeframe:

Up to 86.9 weeks

Notes:

[86] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[87] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[88]	1 ^[89]	1 ^[90]	5 ^[91]
Units: Participants				
Hemoglobin, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	0	0	2
Lymphocytes, n=1,1,0,5,1,4,7,18,3,8,1,7,7,15,6	0	0	77777	3
Neutrophils, n=1,1,0,5,1,4,7,18,3,8,1,7,7,15,5	0	0	77777	4
Platelets, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	0	0	1	4
Leukocytes, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	0	0	1	4

Notes:

[88] - All Treated Population

[89] - All Treated Population

[90] - All Treated Population

[91] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[92]	4 ^[93]	8 ^[94]	18 ^[95]
Units: Participants				
Hemoglobin, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	0	2	3	13
Lymphocytes, n=1,1,0,5,1,4,7,18,3,8,1,7,7,15,6	1	3	4	11
Neutrophils, n=1,1,0,5,1,4,7,18,3,8,1,7,7,15,5	0	3	1	6
Platelets, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	4	4	17
Leukocytes, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	1	3	2	9

Notes:

[92] - All Treated Population

[93] - All Treated Population

[94] - All Treated Population

[95] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[96]	8 ^[97]	1 ^[98]	7 ^[99]
Units: Participants				
Hemoglobin, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	3	6	1	4
Lymphocytes, n=1,1,0,5,1,4,7,18,3,8,1,7,7,15,6	2	5	1	6
Neutrophils, n=1,1,0,5,1,4,7,18,3,8,1,7,7,15,5	2	5	0	2
Platelets, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	3	4	1	5

Leukocytes, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	3	4	1	3
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Notes:

[96] - All Treated Population

[97] - All Treated Population

[98] - All Treated Population

[99] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[100]	16 ^[101]	6 ^[102]	
Units: Participants				
Hemoglobin, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	6	9	3	
Lymphocytes, n=1,1,0,5,1,4,7,18,3,8,1,7,7,15,6	3	10	5	
Neutrophils, n=1,1,0,5,1,4,7,18,3,8,1,7,7,15,5	5	3	1	
Platelets, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	7	11	2	
Leukocytes, n=1,1,1,5,1,4,7,18,3,8,1,7,7,16,6	4	9	3	

Notes:

[100] - All Treated Population

[101] - All Treated Population

[102] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of participants with worst-case urinalysis results post-Baseline relative to Baseline by dipstick method

End point title	Part 1: Number of participants with worst-case urinalysis results post-Baseline relative to Baseline by dipstick method ^{[103][104]}
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End point description:

Urine samples were collected to assess glucose, ketones, occult blood, urine protein, and monoclonal protein (monoclonal pro). The dipstick test gave results in semi-quantitative manner, & results for urinalysis parameters were recorded as negative, trace, 1+, 2+, 3+ indicating proportional concentrations in the urine sample. Any increase was defined as any increase in proportional concentrations relative to Baseline. Baseline was most recent, non-missing value prior to or on the first study treatment dose date. Data for worst-case post Baseline with any increase is presented. Only those participants with data available at the specified data points were analyzed (represented by n=X in category titles). 77777 indicates data is not available.

End point type	Primary
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End point timeframe:

Up to 86.9 weeks

Notes:

[103] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[104] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[105]	1 ^[106]	1 ^[107]	4 ^[108]
Units: Participants				
Glucose, n=1,1,1,4,1,4,4,15, 3,5,0,3,5,8,1	0	0	0	1
Ketones, n=1,1,1,4,1,4,4,13,3,5,1,6,5,11,2	1	0	0	0
Occult blood, n=1,1,1,4,1,4,5,14,3,7,1,6,5,11,2	1	0	1	3
Protein, n=1,1,1,4,1,4,2,12,1,5,0,3,4,7,1	0	0	1	2
Monoclonal pro, n=0,0,0,0,0,1,0,0,2,0,0,0,0,0,0	77777	77777	77777	77777

Notes:

[105] - All Treated Population

[106] - All Treated Population

[107] - All Treated Population

[108] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[109]	4 ^[110]	5 ^[111]	15 ^[112]
Units: Participants				
Glucose, n=1,1,1,4,1,4,4,15, 3,5,0,3,5,8,1	0	1	1	0
Ketones, n=1,1,1,4,1,4,4,13,3,5,1,6,5,11,2	1	0	0	1
Occult blood, n=1,1,1,4,1,4,5,14,3,7,1,6,5,11,2	0	2	3	4
Protein, n=1,1,1,4,1,4,2,12,1,5,0,3,4,7,1	1	2	1	5
Monoclonal pro, n=0,0,0,0,0,1,0,0,2,0,0,0,0,0,0	77777	0	77777	77777

Notes:

[109] - All Treated Population

[110] - All Treated Population

[111] - All Treated Population

[112] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[113]	7 ^[114]	1 ^[115]	6 ^[116]
Units: Participants				
Glucose, n=1,1,1,4,1,4,4,15, 3,5,0,3,5,8,1	0	2	77777	0
Ketones, n=1,1,1,4,1,4,4,13,3,5,1,6,5,11,2	0	2	1	1

Occult blood, n=1,1,1,4,1,4,5,14,3,7,1,6,5,11,2	3	3	1	4
Protein, n=1,1,1,4,1,4,2,12,1,5,0,3,4,7,1	0	3	77777	0
Monoclonal pro, n=0,0,0,0,0,1,0,0,2,0,0,0,0,0,0	0	77777	77777	77777

Notes:

[113] - All Treated Population

[114] - All Treated Population

[115] - All Treated Population

[116] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5 ^[117]	11 ^[118]	2 ^[119]	
Units: Participants				
Glucose, n=1,1,1,4,1,4,4,15, 3,5,0,3,5,8,1	2	2	1	
Ketones, n=1,1,1,4,1,4,4,13,3,5,1,6,5,11,2	0	3	1	
Occult blood, n=1,1,1,4,1,4,5,14,3,7,1,6,5,11,2	2	4	1	
Protein, n=1,1,1,4,1,4,2,12,1,5,0,3,4,7,1	3	3	1	
Monoclonal pro, n=0,0,0,0,0,1,0,0,2,0,0,0,0,0,0	77777	77777	77777	

Notes:

[117] - All Treated Population

[118] - All Treated Population

[119] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of participants with worst case vital signs results relative to Baseline: Pulse rate and body temperature

End point title	Part 1: Number of participants with worst case vital signs results relative to Baseline: Pulse rate and body temperature ^{[120][121]}
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End point description:

Vital signs (pulse rate and temperature) were measured after resting for at least 5 minutes in a supine or semi-recumbent position. The clinical concern ranges were: For pulse rate (low <60 beats per minute [bpm] and high >100 bpm); For body temperature (<=35 degrees Celsius or >=38 degrees Celsius). Participants were counted in the worst case category that their value changed to (low, normal or high), unless there was no change in their category. Participants whose value category was unchanged, or whose value became normal, were recorded in "To Normal or No Change" category. Participants were counted twice if the participant had values that changed "To Low" and "To High", so percentages may not add to 100%. Baseline was most recent, non-missing value prior to or on first study treatment dose date. Only those participants with data available at the specified data points were analyzed.

End point type	Primary
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End point timeframe:

Up to 86.9 weeks

Notes:

[120] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[121] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[122]	1 ^[123]	1 ^[124]	5 ^[125]
Units: Participants				
Pulse rate, To Low	0	0	1	0
Pulse rate, To Normal or No change	0	1	0	2
Pulse Rate, To High	1	0	0	3
Temperature, To Low	0	0	0	0
Temperature, To Normal or No Change	0	1	1	4
Temperature, To High	1	0	0	1

Notes:

[122] - All Treated Population

[123] - All Treated Population

[124] - All Treated Population

[125] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[126]	4 ^[127]	7 ^[128]	18 ^[129]
Units: Participants				
Pulse rate, To Low	0	0	2	0
Pulse rate, To Normal or No change	0	2	4	8
Pulse Rate, To High	1	2	2	10
Temperature, To Low	0	1	0	0
Temperature, To Normal or No Change	1	2	3	15
Temperature, To High	0	1	4	3

Notes:

[126] - All Treated Population

[127] - All Treated Population

[128] - All Treated Population

[129] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[130]	8 ^[131]	1 ^[132]	7 ^[133]
Units: Participants				
Pulse rate, To Low	0	0	0	0
Pulse rate, To Normal or No change	1	5	1	1
Pulse Rate, To High	2	3	0	6

Temperature, To Low	0	0	0	0
Temperature, To Normal or No Change	3	7	1	1
Temperature, To High	0	1	0	6

Notes:

[130] - All Treated Population

[131] - All Treated Population

[132] - All Treated Population

[133] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[134]	16 ^[135]	6 ^[136]	
Units: Participants				
Pulse rate, To Low	0	1	0	
Pulse rate, To Normal or No change	1	8	4	
Pulse Rate, To High	6	8	2	
Temperature, To Low	1	1	0	
Temperature, To Normal or No Change	6	7	6	
Temperature, To High	0	8	0	

Notes:

[134] - All Treated Population

[135] - All Treated Population

[136] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of participants with increase to Grade 3 from Baseline in vital signs: Diastolic Blood pressure (DBP) and Systolic Blood pressure (SBP)

End point title	Part 1: Number of participants with increase to Grade 3 from Baseline in vital signs: Diastolic Blood pressure (DBP) and Systolic Blood pressure (SBP) ^{[137][138]}
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End point description:

DBP and SBP were measured after resting for at least 5 minutes in a supine or semi-recumbent position. They were graded according to NCI-CTCAE version 4.0. For SBP: Grade 0 (≤ 120 millimeter of mercury [mmHg]), Grade 1 (121-139 mmHg), Grade 2 (140-159 mmHg), Grade 3 (≥ 160 mmHg). For DBP: Grade 0 (≤ 80 mmHg), Grade 1 (81-89 mmHg), Grade 2 (90-99 mmHg), Grade 3 (≥ 100 mmHg). Higher grade indicates greater severity. Baseline was the most recent, non-missing value prior to or on the first study treatment dose date. An increase is defined as an increase in grade relative to Baseline grade. Number of participants with increase to Grade 3 from Baseline is presented.

End point type	Primary
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End point timeframe:

Up to 86.9 weeks

Notes:

[137] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[138] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[139]	1 ^[140]	1 ^[141]	5 ^[142]
Units: Participants				
DBP	0	0	0	0
SBP	0	0	0	1

Notes:

[139] - All Treated Population

[140] - All Treated Population

[141] - All Treated Population

[142] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[143]	4 ^[144]	7 ^[145]	18 ^[146]
Units: Participants				
DBP	1	0	0	1
SBP	1	0	1	1

Notes:

[143] - All Treated Population

[144] - All Treated Population

[145] - All Treated Population

[146] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[147]	8 ^[148]	1 ^[149]	7 ^[150]
Units: Participants				
DBP	0	0	0	0
SBP	0	1	1	4

Notes:

[147] - All Treated Population

[148] - All Treated Population

[149] - All Treated Population

[150] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[151]	16 ^[152]	6 ^[153]	
Units: Participants				
DBP	1	0	0	
SBP	1	4	4	

Notes:

[151] - All Treated Population

[152] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of participants with worst-case post-Baseline abnormal electrocardiogram (ECG) findings (investigator reading)

End point title	Part 1: Number of participants with worst-case post-Baseline abnormal electrocardiogram (ECG) findings (investigator reading) ^{[154][155]}
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End point description:

12-lead ECGs were recorded with the participants in a supine position using an ECG machine. Number of participants with worst-case clinically significant and not clinically significant abnormal ECG findings have been presented. Clinically significant abnormal findings are those which are not associated with the underlying disease, unless judged by the investigator to be more severe than expected for the participant's condition.

End point type	Primary
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End point timeframe:

Up to 86.9 weeks

Notes:

[154] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[155] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[156]	1 ^[157]	1 ^[158]	5 ^[159]
Units: Participants				
Abnormal-Clinically significant	0	0	1	1
Abnormal-Not Clinically significant	1	1	0	4

Notes:

[156] - All Treated Population

[157] - All Treated Population

[158] - All Treated Population

[159] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[160]	4 ^[161]	8 ^[162]	18 ^[163]
Units: Participants				
Abnormal-Clinically significant	0	1	1	1

Abnormal-Not Clinically significant	1	3	6	17
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Notes:

[160] - All Treated Population

[161] - All Treated Population

[162] - All Treated Population

[163] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[164]	8 ^[165]	1 ^[166]	7 ^[167]
Units: Participants				
Abnormal-Clinically significant	0	3	0	0
Abnormal-Not Clinically significant	3	5	1	7

Notes:

[164] - All Treated Population

[165] - All Treated Population

[166] - All Treated Population

[167] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[168]	16 ^[169]	6 ^[170]	
Units: Participants				
Abnormal-Clinically significant	2	4	1	
Abnormal-Not Clinically significant	5	12	5	

Notes:

[168] - All Treated Population

[169] - All Treated Population

[170] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 2: Objective response rate (ORR) (MDS cohort)

End point title	Part 2: Objective response rate (ORR) (MDS cohort) ^{[171][172]}
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End point description:

ORR for MDS cohort is defined as the percentage of participants achieving Complete Response (CR), Marrow CR, CRp (as per CR but platelet count $<100 \times 10^9$ cells/Liter[L]), CRi (as per CR but platelet count $<100 \times 10^9$ cells/L or neutrophil count $<1 \times 10^9$ cells/L), or Partial Response (PR) per response criteria. Complete response is defined as bone marrow $\leq 5\%$ myeloblasts with normal maturation of all cell lines, with hemoglobin concentration of ≥ 11 grams per deciliter (g/dL), absolute neutrophil count $\geq 1 \times 10^9$ cells/L, platelet count $\geq 100 \times 10^9$ cells/L and 0% blasts in the peripheral blood. Marrow CR is defined as Bone marrow $\leq 5\%$ myeloblasts and decrease by $\geq 50\%$ over pre-treatment. Objective response rate was determined by the investigator according to international myeloma working group (IMWG) response criteria.

End point type	Primary
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End point timeframe:

Up to 36.4 weeks

Notes:

[171] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[172] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 75 mg QD MDS			
Subject group type	Reporting group			
Number of subjects analysed	16 ^[173]			
Units: Percentage of participants				
number (confidence interval 95%)	25 (7.3 to 52.4)			

Notes:

[173] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Primary: Part 2: Objective response rate lasting at least 4 months (ORR4) (CTCL cohorts)

End point title	Part 2: Objective response rate lasting at least 4 months (ORR4) (CTCL cohorts) ^{[174][175]}
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End point description:

ORR4 for CTCL cohorts is defined as the percentage of participants that have achieved a CR or PR lasting at least 4 months per global response criteria and the modified severity weighted assessment tool (mSWAT). ORR4 and 95% exact confidence interval is presented.

End point type	Primary
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End point timeframe:

Up to 36.4 weeks

Notes:

[174] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There are no statistical data to report.

[175] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 80 mg QD CTCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7 ^[176]	1 ^[177]		
Units: Percentage of participants				
number (confidence interval 95%)	0 (0 to 41)	0 (0 to 97.5)		

Notes:

[176] - All Treated Population

[177] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Overall response rate (ORR)- Investigator assessment

End point title	Part 1: Overall response rate (ORR)- Investigator
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End point description:

ORR is defined as the percentage of participants achieving stringent complete response (sCR), very good partial response (VGPR), partial response (PR) or minimal response (MR) for multiple myeloma (MM); CR or PR for Non-Hodgkin's Lymphoma (NHL); CR, CRp, CRi or PR for Acute Myeloid Leukemia (AML); CR, MR or PR for Myelodysplastic Syndrome (MDS) using the International Working Group (IWG) response criteria and IWG response criteria in myelodysplasia.

End point type	Secondary
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End point timeframe:

Up to 86.9 weeks

Notes:

[178] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[179]	1 ^[180]	1 ^[181]	5 ^[182]
Units: Percentage of participants				
number (confidence interval 95%)	0 (0 to 97.5)	0 (0 to 97.5)	0 (0 to 97.5)	0 (0 to 52.2)

Notes:

[179] - All Treated Population

[180] - All Treated Population

[181] - All Treated Population

[182] - All Treated Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[183]	4 ^[184]	8 ^[185]	18 ^[186]
Units: Percentage of participants				
number (confidence interval 95%)	0 (0 to 97.5)	0 (0 to 60.2)	25 (3.2 to 65.1)	6 (0.1 to 27.3)

Notes:

[183] - All Treated Population

[184] - All Treated Population

[185] - All Treated Population

[186] - All Treated Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[187]	8 ^[188]	1 ^[189]	7 ^[190]
Units: Percentage of participants				
number (confidence interval 95%)	0 (0 to 70.8)	0 (0 to 36.9)	0 (0 to 97.5)	14 (0.4 to

Notes:

[187] - All Treated Population

[188] - All Treated Population

[189] - All Treated Population

[190] - All Treated Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[191]	16 ^[192]	6 ^[193]	
Units: Percentage of participants				
number (confidence interval 95%)	29 (3.7 to 71.0)	13 (1.6 to 38.3)	17 (0.4 to 64.1)	

Notes:

[191] - All Treated Population

[192] - All Treated Population

[193] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Area Under the Concentration-time Curve (AUC) From Time Zero to 24 Hours(AUC[0-24]) and AUC Extrapolated to Infinity (AUC[0-inf]) of GSK525762 following single dose administration

End point title	Part 1: Area Under the Concentration-time Curve (AUC) From Time Zero to 24 Hours(AUC[0-24]) and AUC Extrapolated to Infinity (AUC[0-inf]) of GSK525762 following single dose administration ^[194]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. PK Population consisted of all participants in the All Treated Population for whom a PK sample was obtained and analyzed. Only those participants with data available at the specified data points were analyzed (represented by n=X in category titles). 99999 indicates that, geometric coefficient of variation could not be calculated for single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[194] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[195]	1 ^[196]	1 ^[197]	5 ^[198]
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				

AUC(0-24), n=1,1,1,5,1,4,8,18,3,8,1,6,7,16, 6	460.48 (± 99999)	1024.49 (± 99999)	2881.41 (± 99999)	2146.54 (± 31.68)
AUC(0-inf), n=1,1,1,5,1,4,7,17,3,8,1,5,7,16,5	466.81 (± 99999)	1092.28 (± 99999)	3054.11 (± 99999)	2217.32 (± 32.55)

Notes:

[195] - PK Population

[196] - PK Population

[197] - PK Population

[198] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[199]	4 ^[200]	8 ^[201]	18 ^[202]
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24), n=1,1,1,5,1,4,8,18,3,8,1,6,7,16, 6	3317.10 (± 99999)	2510.55 (± 71.29)	6424.74 (± 22.42)	5918.90 (± 52.85)
AUC(0-inf), n=1,1,1,5,1,4,7,17,3,8,1,5,7,16,5	3465.49 (± 99999)	2546.49 (± 72.05)	6951.06 (± 25.12)	6214.97 (± 60.67)

Notes:

[199] - PK Population

[200] - PK Population

[201] - PK Population

[202] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[203]	8 ^[204]	1 ^[205]	6 ^[206]
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24), n=1,1,1,5,1,4,8,18,3,8,1,6,7,16, 6	3695.32 (± 62.01)	7980.72 (± 45.28)	5944.52 (± 99999)	8394.69 (± 34.31)
AUC(0-inf), n=1,1,1,5,1,4,7,17,3,8,1,5,7,16,5	3874.05 (± 63.27)	8248.45 (± 47.87)	6032.36 (± 99999)	9734.83 (± 29.60)

Notes:

[203] - PK Population

[204] - PK Population

[205] - PK Population

[206] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[207]	16 ^[208]	6 ^[209]	
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24), n=1,1,1,5,1,4,8,18,3,8,1,6,7,16, 6	5017.96 (± 44.17)	13520.57 (± 46.29)	13688.54 (± 43.80)	

AUC(0-inf), n=1,1,1,5,1,4,7,17,3,8,1,5,7,16,5	5114.61 (± 44.76)	14635.17 (± 52.35)	17021.44 (± 35.37)	
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Notes:

[207] - PK Population

[208] - PK Population

[209] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: AUC(0-24) and Area under the concentration-time curve over the dosing interval (AUC[0-tau]) of GSK525762 following repeat dose administration

End point title	Part 1: AUC(0-24) and Area under the concentration-time curve over the dosing interval (AUC[0-tau]) of GSK525762 following repeat dose administration ^[210]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified data points were analyzed. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant. AUC(0-24) represents AUC(0-tau) for repeat dose.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[210] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[211]	1 ^[212]	1 ^[213]	4 ^[214]
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24)	476.71 (± 99999)	656.93 (± 99999)	1855.07 (± 99999)	1908.18 (± 27.53)
AUC(0-tau)	476.71 (± 99999)	656.93 (± 99999)	1855.07 (± 99999)	1908.18 (± 27.53)

Notes:

[211] - PK Population

[212] - PK Population

[213] - PK Population

[214] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[215]	4 ^[216]	3 ^[217]	11 ^[218]
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				

AUC(0-24)	2490.25 (± 99999)	1702.37 (± 58.17)	6271.43 (± 38.76)	3576.49 (± 30.59)
AUC(0-tau)	2490.25 (± 99999)	1702.37 (± 58.17)	6271.43 (± 38.76)	3576.49 (± 30.59)

Notes:

[215] - PK Population

[216] - PK Population

[217] - PK Population

[218] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[219]	7 ^[220]	1 ^[221]	6 ^[222]
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24)	931.02 (± 53.64)	5883.76 (± 48.48)	5188.25 (± 99999)	6892.57 (± 71.96)
AUC(0-tau)	931.02 (± 53.64)	5883.76 (± 48.48)	5188.25 (± 99999)	6892.57 (± 71.96)

Notes:

[219] - PK Population

[220] - PK Population

[221] - PK Population

[222] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4 ^[223]	11 ^[224]	2 ^[225]	
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24)	2994.24 (± 37.27)	9440.98 (± 84.11)	5296.46 (± 8.89)	
AUC(0-tau)	2994.24 (± 37.27)	9440.98 (± 84.11)	5296.46 (± 8.89)	

Notes:

[223] - PK Population

[224] - PK Population

[225] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Maximum Observed Concentration (Cmax) and Minimum plasma concentration (Cmin) of GSK525762 following single dose administration

End point title	Part 1: Maximum Observed Concentration (Cmax) and Minimum plasma concentration (Cmin) of GSK525762 following single dose administration ^[226]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK

parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified data points were analyzed. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant.

End point type	Secondary
End point timeframe:	
Week 1 Day 1: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose	

Notes:

[226] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[227]	1 ^[228]	1 ^[229]	5 ^[230]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax	90.56 (± 99999)	116.69 (± 99999)	559.14 (± 99999)	442.77 (± 31.83)
Cmin	1.11 (± 99999)	27.86 (± 99999)	20.62 (± 99999)	7.55 (± 73.07)

Notes:

[227] - PK Population

[228] - PK Population

[229] - PK Population

[230] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[231]	4 ^[232]	8 ^[233]	18 ^[234]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax	513.03 (± 99999)	660.79 (± 71.94)	853.03 (± 31.1)	1158.66 (± 28.58)
Cmin	21.20 (± 99999)	13.25 (± 71.79)	107.30 (± 68.40)	50.49 (± 139.83)

Notes:

[231] - PK Population

[232] - PK Population

[233] - PK Population

[234] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[235]	8 ^[236]	1 ^[237]	6 ^[238]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				

Cmax	813.87 (± 27.91)	1728.80 (± 35.37)	1248.10 (± 99999)	1444.42 (± 29.92)
Cmin	29.39 (± 47.67)	37.92 (± 80.33)	129.76 (± 99999)	71.43 (± 112.42)

Notes:

[235] - PK Population

[236] - PK Population

[237] - PK Population

[238] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[239]	16 ^[240]	6 ^[241]	
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax	1073.51 (± 38.46)	2335.99 (± 23.05)	1793.39 (± 42.16)	
Cmin	27.89 (± 115.67)	89.96 (± 112.80)	138.75 (± 111.14)	

Notes:

[239] - PK Population

[240] - PK Population

[241] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Cmax and Cmin of GSK525762 following repeat dose administration

End point title	Part 1: Cmax and Cmin of GSK525762 following repeat dose administration ^[242]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified data points were analyzed. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[242] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[243]	1 ^[244]	1 ^[245]	4 ^[246]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax	102.86 (± 99999)	118.59 (± 99999)	550.01 (± 99999)	387.66 (± 52.41)
Cmin	1.47 (± 99999)	5.03 (± 99999)	3.92 (± 99999)	7.72 (± 103.48)

Notes:

[243] - PK Population

[244] - PK Population

[245] - PK Population

[246] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[247]	4 ^[248]	3 ^[249]	11 ^[250]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax	557.60 (± 99999)	566.59 (± 57.75)	1070.32 (± 37.26)	1179.42 (± 28.10)
Cmin	8.66 (± 99999)	2.36 (± 84.21)	57.75 (± 82.69)	7.03 (± 51.10)

Notes:

[247] - PK Population

[248] - PK Population

[249] - PK Population

[250] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[251]	7 ^[252]	1 ^[253]	6 ^[254]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax	512.78 (± 48.37)	1384.46 (± 35.35)	1752.86 (± 99999)	1314.21 (± 58.58)
Cmin	1.63 (± 141.42)	14.00 (± 112.58)	21.02 (± 99999)	50.89 (± 123.69)

Notes:

[251] - PK Population

[252] - PK Population

[253] - PK Population

[254] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
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Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4 ^[255]	11 ^[256]	2 ^[257]	
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax	725.29 (± 46.79)	1587.25 (± 50.83)	921.35 (± 52.16)	
Cmin	4.64 (± 73.29)	55.63 (± 163.06)	14.96 (± 64.95)	

Notes:

[255] - PK Population

[256] - PK Population

[257] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Trough concentration (Ctau) of GSK525762 following repeat dose administration

End point title	Part 1: Trough concentration (Ctau) of GSK525762 following repeat dose administration ^[258]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified data points were analyzed. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: Pre-dose on Days 4, 6 and 7

Notes:

[258] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[259]	1 ^[260]	1 ^[261]	4 ^[262]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	0.91 (± 99999)	3.90 (± 99999)	3.76 (± 99999)	4.88 (± 78.94)

Notes:

[259] - PK Population

[260] - PK Population

[261] - PK Population

[262] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[263]	4 ^[264]	3 ^[265]	11 ^[266]
Units: Nanograms per milliliter (ng/mL)				

geometric mean (geometric coefficient of variation)	8.12 (\pm 99999)	2.26 (\pm 114.63)	32.85 (\pm 88.47)	5.99 (\pm 41.92)
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Notes:

[263] - PK Population

[264] - PK Population

[265] - PK Population

[266] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[267]	7 ^[268]	1 ^[269]	6 ^[270]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	0.03 (\pm 128.56)	13.21 (\pm 102.35)	2.08 (\pm 99999)	15.77 (\pm 123.78)

Notes:

[267] - PK Population

[268] - PK Population

[269] - PK Population

[270] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4 ^[271]	11 ^[272]	2 ^[273]	
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	2.25 (\pm 92.05)	42.18 (\pm 139.74)	14.34 (\pm 68.62)	

Notes:

[271] - PK Population

[272] - PK Population

[273] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Time of maximum concentration (Tmax) of GSK525762 following single dose administration

End point title	Part 1: Time of maximum concentration (Tmax) of GSK525762 following single dose administration ^[274]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified data points were analyzed. 66666 indicates full range could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[274] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[275]	1 ^[276]	1 ^[277]	5 ^[278]
Units: Hour				
median (full range (min-max))	0.62 (-66666 to 66666)	2.00 (-66666 to 66666)	1.00 (-66666 to 66666)	1.00 (0.5 to 1.0)

Notes:

[275] - PK Population

[276] - PK Population

[277] - PK Population

[278] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[279]	4 ^[280]	8 ^[281]	18 ^[282]
Units: Hour				
median (full range (min-max))	1.00 (-66666 to 66666)	0.78 (0.4 to 2.0)	1.56 (0.3 to 2.1)	1.00 (0.3 to 4.1)

Notes:

[279] - PK Population

[280] - PK Population

[281] - PK Population

[282] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[283]	8 ^[284]	1 ^[285]	6 ^[286]
Units: Hour				
median (full range (min-max))	1.00 (0.5 to 2.2)	0.86 (0.5 to 2.1)	1.28 (-66666 to 66666)	1.03 (0.5 to 2.0)

Notes:

[283] - PK Population

[284] - PK Population

[285] - PK Population

[286] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[287]	16 ^[288]	6 ^[289]	
Units: Hour				
median (full range (min-max))	1.00 (0.3 to 1.2)	0.92 (0.3 to 4.0)	1.58 (0.2 to 4.1)	

Notes:

[287] - PK Population

[288] - PK Population

[289] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Tmax of GSK525762 following repeat dose administration

End point title	Part 1: Tmax of GSK525762 following repeat dose administration ^[290]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified data points were analyzed. 66666 indicates full range could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[290] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[291]	1 ^[292]	1 ^[293]	4 ^[294]
Units: Hour				
median (full range (min-max))	0.67 (-66666 to 66666)	0.00 (-66666 to 66666)	0.83 (-66666 to 66666)	1.26 (0.5 to 2.0)

Notes:

[291] - PK Population

[292] - PK Population

[293] - PK Population

[294] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[295]	4 ^[296]	3 ^[297]	11 ^[298]
Units: Hour				
median (full range (min-max))	0.50 (-66666 to 66666)	0.78 (0.5 to 1.2)	0.58 (0.5 to 2.0)	0.50 (0.3 to 2.0)

Notes:

[295] - PK Population

[296] - PK Population

[297] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[299]	7 ^[300]	1 ^[301]	6 ^[302]
Units: Hour				
median (full range (min-max))	0.63 (0.3 to 1.0)	0.60 (0.3 to 0.6)	0.50 (-66666 to 66666)	0.98 (0.5 to 2.0)

Notes:

[299] - PK Population

[300] - PK Population

[301] - PK Population

[302] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4 ^[303]	11 ^[304]	2 ^[305]	
Units: Hour				
median (full range (min-max))	1.06 (0.6 to 2.0)	2.00 (0.5 to 4.0)	2.33 (0.5 to 4.2)	

Notes:

[303] - PK Population

[304] - PK Population

[305] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Terminal half life (T1/2) of GSK525762 following single dose administration

End point title	Part 1: Terminal half life (T1/2) of GSK525762 following single dose administration ^[306]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified data points were analyzed. 66666 indicates full range could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[306] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[307]	1 ^[308]	1 ^[309]	5 ^[310]
Units: Hour				
median (full range (min-max))	4.01 (-66666 to 66666)	5.75 (-66666 to 66666)	6.27 (-66666 to 66666)	4.55 (1.4 to 6.4)

Notes:

[307] - PK Population

[308] - PK Population

[309] - PK Population

[310] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[311]	4 ^[312]	8 ^[313]	17 ^[314]
Units: Hour				
median (full range (min-max))	5.10 (-66666 to 66666)	4.07 (3.5 to 4.6)	6.48 (5.2 to 10.3)	3.96 (2.9 to 9.3)

Notes:

[311] - PK Population

[312] - PK Population

[313] - PK Population

[314] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[315]	8 ^[316]	1 ^[317]	5 ^[318]
Units: Hour				
median (full range (min-max))	5.55 (1.4 to 8.1)	4.57 (3.3 to 6.3)	4.15 (-66666 to 66666)	4.75 (4.1 to 7.4)

Notes:

[315] - PK Population

[316] - PK Population

[317] - PK Population

[318] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[319]	16 ^[320]	5 ^[321]	
Units: Hour				
median (full range (min-max))	4.06 (3.0 to 5.8)	5.66 (1.9 to 9.7)	6.53 (4.7 to 7.5)	

Notes:

[319] - PK Population

[320] - PK Population

[321] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: T1/2 of GSK525762 following repeat dose administration

End point title	Part 1: T1/2 of GSK525762 following repeat dose administration ^[322]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified data points were analyzed. 66666 indicates full range could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[322] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[323]	1 ^[324]	1 ^[325]	4 ^[326]
Units: Hour				
median (full range (min-max))	3.68 (-66666 to 66666)	5.64 (-66666 to 66666)	4.70 (-66666 to 66666)	4.15 (2.9 to 6.4)

Notes:

[323] - PK Population

[324] - PK Population

[325] - PK Population

[326] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[327]	4 ^[328]	3 ^[329]	11 ^[330]
Units: Hour				
median (full range (min-max))	4.39 (-66666 to 66666)	4.39 (3.2 to 5.8)	6.48 (3.4 to 7.8)	3.51 (3.0 to 5.3)

Notes:

[327] - PK Population

[328] - PK Population

[329] - PK Population

[330] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[331]	6 ^[332]	1 ^[333]	6 ^[334]
Units: Hour				
median (full range (min-max))	1.96 (1.7 to	3.97 (3.1 to	2.54 (-66666	4.98 (2.4 to

	2.3)	5.3)	to 66666)	5.9)
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Notes:

[331] - PK Population

[332] - PK Population

[333] - PK Population

[334] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4 ^[335]	11 ^[336]	2 ^[337]	
Units: Hour				
median (full range (min-max))	3.22 (2.2 to 3.7)	5.51 (3.2 to 8.6)	4.09 (3.8 to 4.4)	

Notes:

[335] - PK Population

[336] - PK Population

[337] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Time invariance (RS) of GSK525762

End point title	Part 1: Time invariance (RS) of GSK525762 ^[338]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. RS was calculated by taking ratio of AUC(0-24) on Week 2 Day 7 to AUC(0-inf) on Week 1 Day 1. PK parameters were calculated by standard non-compartmental analysis. Only those participants with data available at the specified data points were analyzed. 99999 indicates geometric coefficient of variation could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose; Week 2 Day 7: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[338] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[339]	1 ^[340]	1 ^[341]	5 ^[342]
Units: Ratio				
geometric mean (geometric coefficient of variation)	1.02 (± 99999)	0.60 (± 99999)	0.61 (± 99999)	0.71 (± 35.82)

Notes:

[339] - PK Population

[340] - PK Population

[341] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[343]	4 ^[344]	3 ^[345]	10 ^[346]
Units: Ratio				
geometric mean (geometric coefficient of variation)	0.72 (± 99999)	0.67 (± 18.60)	0.98 (± 11.73)	0.65 (± 31.37)

Notes:

[343] - PK Population

[344] - PK Population

[345] - PK Population

[346] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[347]	7 ^[348]	1 ^[349]	7 ^[350]
Units: Ratio				
geometric mean (geometric coefficient of variation)	0.32 (± 53.56)	0.78 (± 46.56)	0.86 (± 99999)	0.91 (± 36.22)

Notes:

[347] - PK Population

[348] - PK Population

[349] - PK Population

[350] - PK Population

End point values	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	Part 1: GSK525762 120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4 ^[351]	11 ^[352]	1 ^[353]	
Units: Ratio				
geometric mean (geometric coefficient of variation)	0.74 (± 19.36)	0.76 (± 84.74)	0.54 (± 99999)	

Notes:

[351] - PK Population

[352] - PK Population

[353] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Accumulation ratio (RO) of GSK525762

End point title	Part 1: Accumulation ratio (RO) of GSK525762 ^[354]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. Accumulation ratio was calculated by taking ratio of AUC(0-24) in Week 2 Day 7 to AUC (0-24) in Week 1 Day 1. PK parameters were calculated by standard non-compartmental analysis. Only those participants with data

available at the specified data points were analyzed. 99999 indicates geometric coefficient of variation could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose; Week 2 Day 7: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[354] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 5 mg QD	Part 1: GSK525762 10 mg QD	Part 1: GSK525762 20 mg QD	Part 1: GSK525762 30 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[355]	1 ^[356]	1 ^[357]	4 ^[358]
Units: Ratio				
geometric mean (geometric coefficient of variation)	1.04 (± 99999)	0.64 (± 99999)	0.64 (± 99999)	0.74 (± 36.67)

Notes:

[355] - PK Population

[356] - PK Population

[357] - PK Population

[358] - PK Population

End point values	Part 1: GSK525762 40 mg QD	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD AML	Part 1: GSK525762 60 mg QD NHL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1 ^[359]	4 ^[360]	3 ^[361]	11 ^[362]
Units: Ratio				
geometric mean (geometric coefficient of variation)	0.75 (± 99999)	0.68 (± 17.66)	1.06 (± 13.47)	0.67 (± 29.24)

Notes:

[359] - PK Population

[360] - PK Population

[361] - PK Population

[362] - PK Population

End point values	Part 1: GSK525762 60 mg QD MM	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD	Part 1: GSK525762 80 mg QD AML
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[363]	7 ^[364]	1 ^[365]	5 ^[366]
Units: Ratio				
geometric mean (geometric coefficient of variation)	0.33 (± 47.64)	0.81 (± 45.70)	0.87 (± 99999)	1.01 (± 33.69)

Notes:

[363] - PK Population

[364] - PK Population

[365] - PK Population

[366] - PK Population

End point values	Part 1: GSK525762 80	Part 1: GSK525762	Part 1: GSK525762	
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	mg QD NHL	100 mg QD AML	120 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	4 ^[367]	11 ^[368]	2 ^[369]	
Units: Ratio				
geometric mean (geometric coefficient of variation)	0.75 (± 20.27)	0.81 (± 82.45)	0.71 (± 24.96)	

Notes:

[367] - PK Population

[368] - PK Population

[369] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Apparent clearance (CL/F) of GSK525762 after single dose administration

End point title	Part 2: Apparent clearance (CL/F) of GSK525762 after single dose administration ^[370]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by empirical Bayes estimates. GSK525762 plasma concentration-time data was analyzed by Population PK methods using a non-linear mixed-effects modelling approach. Given only one participant at 80 mg for single dose data, population PK analysis of combined data from 75 mg QD and 80 mg QD CTCL was more appropriate. Hence the single participant of 80 mg QD arm was included in 75 mg QD MDS arm which leads to "N" of 75 mg arm within this outcome measure is greater than overall "N" for 75 mg QD MDS & N=0 for 80 mg QC CTCL arm for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: pre-dose and at 0.5 – 2 hour, 4 – 8 hours post-dose

Notes:

[370] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	7 ^[371]	17 ^[372]		
Units: Liters per hour				
arithmetic mean (standard deviation)	11.80 (± 3.39)	7.98 (± 3.32)		

Notes:

[371] - PK Population.

[372] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Apparent clearance (CL/F) of GSK525762 after repeat dose administration

End point title	Part 2: Apparent clearance (CL/F) of GSK525762 after repeat dose administration ^[373]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by empirical Bayes estimates. GSK525762 plasma concentration-time data was analyzed by Population PK methods using a non-linear mixed-effects modelling approach. Given only one participant at 80 mg for single dose data, population PK analysis of combined data from 75 mg QD and 80 mg QD CTCL was more appropriate. Hence the single participant of 80 mg QD arm was included in 75 mg QD MDS arm which leads to "N=0" for 80 mg QD arm within this outcome measure.

End point type	Secondary
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End point timeframe:

Week 3 Day 1: pre-dose and at 0.5 – 2 hour, 4 – 8 hours post-dose

Notes:

[373] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7 ^[374]	8 ^[375]		
Units: Liters per hour				
arithmetic mean (standard deviation)	11.80 (± 3.39)	9.33 (± 4.01)		

Notes:

[374] - PK Population

[375] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Apparent central volume of distribution (V1/F) of GSK525762 following single dose administration

End point title	Part 2: Apparent central volume of distribution (V1/F) of GSK525762 following single dose administration ^[376]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by empirical Bayes estimates. GSK525762 plasma concentration-time data was analyzed by Population PK methods using a non-linear mixed-effects modelling approach. Given only one participant at 80 mg for single dose data, population PK analysis of combined data from 75 mg QD and 80 mg QD CTCL was more appropriate. Hence the single participant of 80 mg QD arm was included in 75 mg QD MDS arm which leads to "N" of 75 mg arm within this outcome measure is greater than overall "N" for 75 mg QD MDS N=0 for 80 mg QC CTCL arm for this outcome measure.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: pre-dose and at 0.5 – 2 hour, 4 – 8 hours post-dose

Notes:

[376] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	7 ^[377]	17 ^[378]		
Units: Liters				
arithmetic mean (standard deviation)	51.5 (± 19.50)	47.9 (± 8.01)		

Notes:

[377] - PK Population

[378] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Apparent central volume of distribution (V1/F) of GSK525762 following repeat dose administration

End point title	Part 2: Apparent central volume of distribution (V1/F) of GSK525762 following repeat dose administration ^[379]
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End point description:

Plasma samples for PK analysis of GSK525762 were collected at the indicated time points. PK parameters were calculated by empirical Bayes estimates. GSK525762 plasma concentration-time data was analyzed by Population PK methods using a non-linear mixed-effects modelling approach. Given only one participant at 80 mg for single dose data, population PK analysis of combined data from 75 mg QD and 80 mg QD CTCL was more appropriate. Hence the single participant of 80 mg QD arm was included in 75 mg QD MDS arm which leads to "N=0" for 80 mg QD arm within this outcome measure.

End point type	Secondary
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End point timeframe:

Week 3 Day 1: pre-dose and at 0.5 – 2 hour, 4 – 8 hours post-dose

Notes:

[379] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7 ^[380]	8 ^[381]		
Units: Liters				
arithmetic mean (standard deviation)	51.5 (± 19.50)	45.8 (± 9.92)		

Notes:

[380] - PK population

[381] - PK population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: AUC(0-24) and AUC[0-inf] of GSK3529246 (active metabolite) following single dose administration

End point title	Part 1: AUC(0-24) and AUC[0-inf] of GSK3529246 (active metabolite) following single dose administration ^[382]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time

points. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed (represented by n=X in category titles). Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[382] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[383]	1 ^[384]	15 ^[385]	2 ^[386]
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24), n=0,0,0,5,0,1,0,15, 2,8,0,0,6,15,0	1368.11 (± 31.39)	1891.48 (± 99999)	3048.33 (± 22.85)	3297.95 (± 68.31)
AUC(0-inf), n=0,0,0,5,0,1,0,10, 2,7,0,0,6,7,0	1691.75 (± 28.96)	2013.33 (± 99999)	3684.96 (± 28.50)	4499.65 (± 72.79)

Notes:

[383] - PK Population

[384] - PK Population

[385] - PK Population

[386] - PK Population

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8 ^[387]	6 ^[388]	15 ^[389]	
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24), n=0,0,0,5,0,1,0,15, 2,8,0,0,6,15,0	3174.42 (± 40.63)	3432.89 (± 39.76)	2901.79 (± 52.33)	
AUC(0-inf), n=0,0,0,5,0,1,0,10, 2,7,0,0,6,7,0	4003.48 (± 42.09)	3908.15 (± 41.20)	4714.85 (± 48.39)	

Notes:

[387] - PK Population

[388] - PK Population

[389] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: AUC(0-24) and AUC(0-tau) of GSK3529246 (active metabolite) following repeat dose administration

End point title	Part 1: AUC(0-24) and AUC(0-tau) of GSK3529246 (active metabolite) following repeat dose administration ^[390]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed. Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 12 mg QD AML. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant. AUC(0-tau) is AUC(0-24) for repeat dose.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[390] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[391]	1 ^[392]	9 ^[393]	2 ^[394]
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24)	1517.96 (± 33.88)	1922.77 (± 99999)	4870.28 (± 46.15)	3838.35 (± 37.18)
AUC(0-tau)	1517.96 (± 33.88)	1922.77 (± 99999)	4870.28 (± 46.15)	3838.35 (± 37.18)

Notes:

[391] - PK Population

[392] - PK Population

[393] - PK Population

[394] - PK Population

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[395]	4 ^[396]	10 ^[397]	
Units: Hours*nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
AUC(0-24)	5312.66 (± 45.30)	3379.85 (± 44.24)	8534.92 (± 43.93)	
AUC(0-tau)	5312.66 (± 45.30)	3379.85 (± 44.24)	8534.92 (± 43.93)	

Notes:

[395] - PK Population

[396] - PK Population

[397] - PK Population

Statistical analyses

Secondary: Part 1: Cmax and Cmin of GSK3529246 (active metabolite) following single dose administration

End point title	Part 1: Cmax and Cmin of GSK3529246 (active metabolite) following single dose administration ^[398]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed (represented by n=X in category titles). Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[398] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[399]	1 ^[400]	15 ^[401]	3 ^[402]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax, n=0,0,0,5,0,1, 0,15,3,8,0,0,7,16,0	109.45 (± 45.38)	246.12 (± 99999)	239.98 (± 26.75)	361.30 (± 54.77)
Cmin, n=0,0,0,2,0,1, 0,14,3,7,0,0,6,13,0	2.47 (± 4.29)	66.39 (± 99999)	18.17 (± 116.63)	10.83 (± 161.52)

Notes:

[399] - PK Population

[400] - PK Population

[401] - PK Population

[402] - PK Population

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8 ^[403]	7 ^[404]	16 ^[405]	
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax, n=0,0,0,5,0,1, 0,15,3,8,0,0,7,16,0	251.73 (± 49.71)	325.42 (± 47.17)	201.02 (± 56.94)	
Cmin, n=0,0,0,2,0,1, 0,14,3,7,0,0,6,13,0	18.45 (± 71.98)	12.66 (± 108.08)	14.17 (± 99.02)	

Notes:

[403] - PK Population

[404] - PK Population

[405] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Cmax and Cmin of GSK3529246 (active metabolite) following repeat dose administration

End point title	Part 1: Cmax and Cmin of GSK3529246 (active metabolite) following repeat dose administration ^[406]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed. Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[406] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[407]	1 ^[408]	9 ^[409]	2 ^[410]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Cmax	121.83 (± 26.75)	282.72 (± 99999)	453.89 (± 34.07)	500.61 (± 22.83)
Cmin	27.14 (± 28.38)	15.18 (± 99999)	66.49 (± 81.56)	40.88 (± 45.39)

Notes:

[407] - PK Population.

[408] - PK Population.

[409] - PK Population.

[410] - PK Population.

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[411]	4 ^[412]	11 ^[413]	
Units: Nanograms per milliliter (ng/mL)				

geometric mean (geometric coefficient of variation)				
Cmax	445.47 (± 52.02)	370.67 (± 35.23)	557.92 (± 31.81)	
Cmin	73.60 (± 88.34)	38.71 (± 56.34)	116.62 (± 74.25)	

Notes:

[411] - PK Population.

[412] - PK Population.

[413] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Trough concentration (Ctau) of GSK3529246 (active metabolite) following repeat dose administration

End point title	Part 1: Trough concentration (Ctau) of GSK3529246 (active metabolite) following repeat dose administration ^[414]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed. Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: Pre-dose on Days 4, 6 and 7

Notes:

[414] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[415]	1 ^[416]	9 ^[417]	2 ^[418]
Units: Nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	22.48 (± 36.13)	13.26 (± 99999)	64.57 (± 77.46)	40.42 (± 43.96)

Notes:

[415] - PK Population.

[416] - PK Population.

[417] - PK Population.

[418] - PK Population.

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[419]	4 ^[420]	10 ^[421]	
Units: Nanograms per milliliter (ng/mL)				

geometric mean (geometric coefficient of variation)	76.23 (± 62.65)	28.29 (± 94.01)	178.76 (± 69.25)	
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Notes:

[419] - PK Population.

[420] - PK Population.

[421] - PK Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Tmax of GSK3529246 (active metabolite) following single dose administration

End point title	Part 1: Tmax of GSK3529246 (active metabolite) following single dose administration ^[422]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed. Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 66666 indicates full range could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[422] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[423]	1 ^[424]	15 ^[425]	3 ^[426]
Units: Hour				
median (full range (min-max))	1.92 (0.9 to 4.1)	0.58 (-66666 to 66666)	2.10 (0.5 to 8.0)	4.00 (2.0 to 4.2)

Notes:

[423] - PK Population

[424] - PK Population

[425] - PK Population

[426] - PK Population

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8 ^[427]	7 ^[428]	16 ^[429]	
Units: Hour				
median (full range (min-max))	3.15 (1.2 to 4.1)	2.08 (0.3 to 4.2)	4.03 (2.0 to 17.5)	

Notes:

[427] - PK Population

[428] - PK Population

[429] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Tmax of GSK3529246 (active metabolite) following repeat dose administration

End point title	Part 1: Tmax of GSK3529246 (active metabolite) following repeat dose administration ^[430]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed. Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 6 mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 66666 indicates full range could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[430] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[431]	1 ^[432]	9 ^[433]	2 ^[434]
Units: Hour				
median (full range (min-max))	2.48 (1.0 to 4.0)	0.60 (-66666 to 66666)	1.03 (0.5 to 4.0)	1.00 (1.0 to 1.0)

Notes:

[431] - PK Population

[432] - PK Population

[433] - PK Population

[434] - PK Population

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[435]	4 ^[436]	11 ^[437]	
Units: Hour				
median (full range (min-max))	2.05 (0.6 to 4.0)	2.02 (1.2 to 4.1)	4.00 (0.9 to 10.1)	

Notes:

[435] - PK Population

[436] - PK Population

[437] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: T1/2 of GSK3529246 (active metabolite) following single dose administration

End point title	Part 1: T1/2 of GSK3529246 (active metabolite) following single dose administration ^[438]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed. Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 66666 indicates full range could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[438] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[439]	1 ^[440]	11 ^[441]	2 ^[442]
Units: Hour				
median (full range (min-max))	9.90 (5.2 to 13.4)	5.83 (-66666 to 66666)	8.66 (6.7 to 14.1)	12.72 (11.5 to 13.9)

Notes:

[439] - PK Population

[440] - PK Population

[441] - PK Population

[442] - PK Population

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6 ^[443]	6 ^[444]	7 ^[445]	
Units: Hour				
median (full range (min-max))	8.31 (5.4 to 15.7)	7.16 (6.3 to 9.1)	9.23 (5.1 to 15.7)	

Notes:

[443] - PK Population

[444] - PK Population

[445] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: T1/2 of GSK3529246 (active metabolite) following repeat dose administration

End point title	Part 1: T1/2 of GSK3529246 (active metabolite) following repeat dose administration ^[446]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed. Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 66666 indicates full range could not be calculated due to single participant.

End point type	Secondary
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End point timeframe:

Week 2 Day 7: Pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[446] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[447]	1 ^[448]	9 ^[449]	2 ^[450]
Units: Hour				
median (full range (min-max))	8.24 (7.7 to 10.0)	6.19 (-66666 to 66666)	7.97 (5.7 to 12.4)	7.39 (7.3 to 7.5)

Notes:

[447] - PK Population

[448] - PK Population

[449] - PK Population

[450] - PK Population

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6 ^[451]	4 ^[452]	8 ^[453]	
Units: Hour				
median (full range (min-max))	8.00 (5.8 to 10.5)	6.72 (4.0 to 8.7)	11.77 (6.9 to 23.8)	

Notes:

[451] - PK Population

[452] - PK Population

[453] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Time invariance (RS) of GSK3529246 (active metabolite)

End point title	Part 1: Time invariance (RS) of GSK3529246 (active metabolite) ^[454]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. RS was calculated by taking ratio of AUC(0-24) on Week 2 Day 7 to AUC(0-inf) on Week 1 Day 1. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed. Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose; Week 2 Day 7: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[454] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[455]	1 ^[456]	8 ^[457]	1 ^[458]
Units: Ratio				
geometric mean (geometric coefficient of variation)	0.92 (± 25.58)	0.96 (± 99999)	1.18 (± 32.33)	0.63 (± 99999)

Notes:

[455] - PK Population

[456] - PK Population

[457] - PK Population

[458] - PK Population

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6 ^[459]	4 ^[460]	6 ^[461]	
Units: Ratio				
geometric mean (geometric coefficient of variation)	1.20 (± 13.74)	1.06 (± 9.48)	1.87 (± 57.15)	

Notes:

[459] - PK Population

[460] - PK Population

[461] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Accumulation ratio (RO) of GSK3529246 (active metabolite)

End point title	Part 1: Accumulation ratio (RO) of GSK3529246 (active metabolite) ^[462]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. Accumulation ratio was calculated by taking ratio of AUC(0-24) in Week 2 Day 7 to AUC (0-24) in Week 1 Day 1. PK parameters were calculated by standard non-compartmental analysis. GSK3529246 is a metabolite of GSK525762. Only those participants with data available at the specified data points were analyzed. Plasma samples were not collected for analysis of GSK3529246 (active metabolite) for cohort GSK525762 5mg QD, 10mg QD, 20mg QD, 40mg QD, 60mg QD AML, 80mg QD, 80mg QD AML, 120mg QD AML. 99999 indicates that, geometric coefficient of variation could not be calculated for single participant

End point type	Secondary
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End point timeframe:

Week 1 Day 1: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose; Week 2 Day 7: pre-dose and at 0.25, 0.5, 1, 2, 4, 8, 12 and 24 hours post-dose

Notes:

[462] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 1: GSK525762 30 mg QD MM	Part 1: GSK525762 40 mg QD MM	Part 1: GSK525762 60 mg QD NHL	Part 1: GSK525762 60 mg QD MM
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4 ^[463]	1 ^[464]	9 ^[465]	1 ^[466]
Units: Ratio				
geometric mean (geometric coefficient of variation)	1.18 (± 25.71)	1.02 (± 99999)	1.61 (± 31.61)	0.90 (± 99999)

Notes:

[463] - PK Population

[464] - PK Population

[465] - PK Population

[466] - PK Population

End point values	Part 1: GSK525762 75 mg QD AML	Part 1: GSK525762 80 mg QD NHL	Part 1: GSK525762 100 mg QD AML	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[467]	4 ^[468]	9 ^[469]	
Units: Ratio				
geometric mean (geometric coefficient of variation)	1.56 (± 26.04)	1.20 (± 11.50)	3.22 (± 59.05)	

Notes:

[467] - PK Population

[468] - PK Population

[469] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Apparent clearance (CL/F) of GSK3529246 (active metabolite) following single dose administration

End point title	Part 2: Apparent clearance (CL/F) of GSK3529246 (active metabolite) following single dose administration ^[470]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. GSK3529246 is a metabolite of GSK525762. PK parameters were calculated by empirical Bayes estimates. GSK3529246 plasma concentration-time data was analyzed by Population PK methods using a non-linear mixed-effects modelling approach. Given only one participant at 80 mg for single dose data, population PK analysis of combined data from 75 mg QD and 80 mg QD CTCL was more appropriate. Hence the single participant of 80 mg QD arm was included in 75 mg QD MDS arm which leads to "N" of 75 mg arm within this outcome measure is greater than overall "N" for 75 mg QD MDS & N=0 for 80 mg QD CTCL.

End point type	Secondary
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End point timeframe:

Week 1 Day 1: pre-dose and at 0.5 – 2 hours, 4 – 8 hours post-dose

Notes:

[470] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	7 ^[471]	17 ^[472]		
Units: Liters per hour				
arithmetic mean (standard deviation)	16.5 (± 7.71)	15.8 (± 6.97)		

Notes:

[471] - PK Population

[472] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Apparent clearance (CL/F) of GSK3529246 (active metabolite) following repeat dose administration

End point title	Part 2: Apparent clearance (CL/F) of GSK3529246 (active metabolite) following repeat dose administration ^[473]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. GSK3529246 is a metabolite of GSK525762. PK parameters were calculated by empirical Bayes estimates. GSK3529246 plasma concentration-time data was analyzed by Population PK methods using a non-linear mixed-effects modelling approach. Given only one participant at 80 mg for single dose data,

population PK analysis of combined data from 75 mg QD and 80 mg QD CTCL was more appropriate. Hence the single participant of 80 mg QD arm was included in 75 mg QD MDS arm which leads to "N=0" for 80 mg QD arm within this outcome measure.

End point type	Secondary
End point timeframe:	
Week 1 Day 1: pre-dose and at 0.5 – 2 hours, 4 – 8 hours post-dose	

Notes:

[473] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7 ^[474]	8 ^[475]		
Units: Liters per hour				
arithmetic mean (standard deviation)	15.9 (± 7.26)	14.6 (± 8.07)		

Notes:

[474] - PK Population

[475] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Apparent central volume of distribution (V1/F) of GSK3529246 (active metabolite) following single dose administration

End point title	Part 2: Apparent central volume of distribution (V1/F) of GSK3529246 (active metabolite) following single dose administration ^[476]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. GSK3529246 is a metabolite of GSK525762. PK parameters were calculated by empirical Bayes estimates. GSK3529246 plasma concentration-time data was analyzed by Population PK methods using a non-linear mixed-effects modelling approach. Given only one participant at 80 mg for single dose data, population PK analysis of combined data from 75 mg QD and 80 mg QD CTCL was more appropriate. Hence the single participant of 80 mg QD arm was included in 75 mg QD MDS arm which leads to "N" of 75 mg arm within this outcome measure is greater than overall "N" for 75 mg QD MDS & N=0 for 80 mg QD CTCL.

End point type	Secondary
End point timeframe:	
Week 1 Day 1: pre-dose and at 0.5 – 2 hours, 4 – 8 hours post-dose	

Notes:

[476] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	7 ^[477]	17 ^[478]		
Units: Liters				
arithmetic mean (standard deviation)	80.0 (± 37.1)	71.5 (± 28.4)		

Notes:

[477] - PK Population

[478] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Apparent central volume of distribution (V1/F) of GSK3529246 (active metabolite) following repeat dose administration

End point title	Part 2: Apparent central volume of distribution (V1/F) of GSK3529246 (active metabolite) following repeat dose administration ^[479]
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End point description:

Plasma samples for PK analysis of GSK3529246 (active metabolite) were collected at the indicated time points. GSK3529246 is a metabolite of GSK525762. PK parameters were calculated by empirical Bayes estimates. GSK3529246 plasma concentration-time data was analyzed by Population PK methods using a non-linear mixed-effects modelling approach. Given only one participant at 80 mg for single dose data, population PK analysis of combined data from 75 mg QD and 80 mg QD CTCL was more appropriate. Hence the single participant of 80 mg QD arm was included in 75 mg QD MDS arm which leads to "N=0" for 80 mg QD arm within this outcome measure.

End point type	Secondary
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End point timeframe:

Week 3 Day 1: pre-dose and at 0.5 – 2 hours, 4 – 8 hours post-dose

Notes:

[479] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7 ^[480]	8 ^[481]		
Units: Liters				
arithmetic mean (standard deviation)	80.0 (± 37.1)	63.4 (± 30.6)		

Notes:

[480] - PK Population

[481] - PK Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change from Baseline in Skindex-29 domain scores (emotional, functioning and symptoms score) for CTCL cohort

End point title	Part 2: Change from Baseline in Skindex-29 domain scores (emotional, functioning and symptoms score) for CTCL cohort ^[482]
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End point description:

Effects of treatment on disease-related symptoms/quality of life was assessed using Skindex-29 Questionnaire, which inquires, how often (Never, Rarely, Sometime, Often, All time) during previous 4 weeks participants experienced effect described in each 29 items divided in 3 domains: Emotional (10 items), Symptoms (7 items), Functioning (12 items). Responses to each item are transformed to linear scale of 100, varying from 0 (no effect) to 100 (effect experienced all time). Skindex-29 scores were reported as 3 individual domain scale scores; scale score is mean of participant's response to items in given domain. Each domain score ranges from 0 (no effect) to 100 (effect experienced all time), higher score implies higher impact of skin disease. Baseline was most recent non-missing value prior to/on first study treatment dose date. Change from Baseline is postdose visit value - Baseline. Only those participants with data available at specified points were analyzed (n=X). 88888 (SD could not be calculated for single participant). 77777 (data

End point type Secondary

End point timeframe:

Baseline (pre-dose Week 1 Day 1) and Week 3, Week 7, Week 10, Week 16 and Week 24

Notes:

[482] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 80 mg QD CTCL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7 ^[483]	1 ^[484]		
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Emotional score, Week 3, n=6,1	-5.83 (± 15.221)	9.17 (± 88888)		
Emotional score, Week 7, n=5,0	-19.50 (± 22.735)	77777 (± 77777)		
Emotional score, Week 10, n=3,0	-44.17 (± 26.497)	77777 (± 77777)		
Emotional score, Week 16, n=3,0	-10.00 (± 10.897)	77777 (± 77777)		
Emotional score, Week 24, n=2,0	-18.75 (± 1.768)	77777 (± 77777)		
Functioning score, Week 3, n=6,1	-1.42 (± 7.742)	30.87 (± 88888)		
Functioning score, Week 7, n=5,0	-13.37 (± 23.000)	77777 (± 77777)		
Functioning score, Week 10, n=3,0	-35.67 (± 27.820)	77777 (± 77777)		
Functioning score, Week 16, n=3,0	-13.45 (± 9.788)	77777 (± 77777)		
Functioning score, Week 24, n=2,0	-18.84 (± 11.919)	77777 (± 77777)		
Symptoms score, Week 3, n=6,1	6.55 (± 24.055)	12.50 (± 88888)		
Symptoms score, Week 7, n=5,0	-2.14 (± 18.489)	77777 (± 77777)		
Symptoms score, Week 10, n=3,0	-29.76 (± 20.927)	77777 (± 77777)		
Symptoms score, Week 16, n=3,0	-8.33 (± 19.670)	77777 (± 77777)		
Symptoms score, Week 24, n=2,0	-14.29 (± 10.102)	77777 (± 77777)		

Notes:

[483] - All Treated Population

[484] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with non-serious AEs and SAEs and AELDs

End point title	Part 2: Number of participants with non-serious AEs and SAEs and AELDs ^[485]
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End point description:

An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and SAE is defined as any untoward medical occurrence that, at any dose which results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or, is a congenital anomaly/birth defect. AELD is adverse events leading to permanent discontinuation of study treatment.

End point type	Secondary
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End point timeframe:

Up to 36.4 weeks

Notes:

[485] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[486]	16 ^[487]	1 ^[488]	
Units: Participants				
Non-serious AEs	7	16	1	
SAEs	5	12	1	
AELD	0	9	0	

Notes:

[486] - All Treated Population

[487] - All Treated Population

[488] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with dose reductions

End point title	Part 2: Number of participants with dose reductions ^[489]
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End point description:

Number of participants with dose reductions due to any reason is presented.

End point type	Secondary
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End point timeframe:

Up to 36.4 weeks

Notes:

[489] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[490]	16 ^[491]	1 ^[492]	
Units: Participants	6	7	0	

Notes:

[490] - All Treated Population

[491] - All Treated Population

[492] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with dose interruptions/delays

End point title	Part 2: Number of participants with dose
End point description: Number of participants with any dose interruptions or delays is presented.	
End point type	Secondary

End point timeframe:

Up to 36.4 weeks

Notes:

[493] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[494]	16 ^[495]	1 ^[496]	
Units: Participants	7	13	1	

Notes:

[494] - All Treated Population

[495] - All Treated Population

[496] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with grade change from Baseline in clinical chemistry parameters

End point title	Part 2: Number of participants with grade change from Baseline in clinical chemistry parameters ^[497]
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End point description:

Blood samples were collected for the analysis of following clinical chemistry parameters: glucose, Prothrombin international normalized ratio (Pro. INR), albumin, amylase, ALT, AST, bilirubin, calcium, calcium ionized, cholesterol, creatinine, creatine kinase, lipase, potassium, magnesium, sodium, Triglycerides, ALP. Laboratory parameters were graded according to NCI-CTCAE version 4.0. Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; Grade 4: life-threatening consequences; Grade 5: death related to AE. Higher grade indicates greater severity. An increase was defined as an increase relative to Baseline. Baseline was the most recent, non-missing value prior to or on the first study treatment dose date. Data for worst-case post Baseline with any grade increase is presented. Only those participants with data available at the specified data points were analyzed (represented by n=X in category titles). 77777 indicates data is not available.

End point type	Secondary
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End point timeframe:

Up to 36.4 weeks

Notes:

[497] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[498]	16 ^[499]	1 ^[500]	
Units: Participants				
Glucose, n=7,16,1	6	14	1	
Pro.INR, n=4,13,0	2	5	77777	
Albumin, n=7,16,1	1	9	1	
ALT, n=7,16,1	4	4	0	
Amylase, n=7,15,1	3	1	1	
AST, n=7,15,1	3	6	1	
Bilirubin, n=7,16,1	3	10	0	
Calcium, n=7,16,1	1	2	1	
Calcium Ionized, n=7,16,1	2	9	0	
Cholesterol, n=7,15,1	2	1	0	
Creatine Kinase, n=5,11,1	1	1	0	
Creatinine, n=7,16,1	0	4	0	
Lipase, n=7,13,1	2	2	1	
Magnesium, n=7,16,1	2	7	0	
Sodium, n=7,16,1	4	6	1	
Triglycerides, n=7,15,1	7	6	0	
ALP, n=7,16,1	2	1	0	

Notes:

[498] - All Treated Population

[499] - All Treated Population

[500] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with grade change from Baseline in

hematology parameters

End point title	Part 2: Number of participants with grade change from Baseline in hematology parameters ^[501]
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End point description:

Blood samples were collected for the analysis of following hematology parameters: hemoglobin, lymphocytes, neutrophils, platelets and leukocytes. The laboratory parameters were graded according to NCI-CTCAE version 4.0. Grade 1: mild; Grade 2: moderate; Grade 3: severe or medically significant; Grade 4: life-threatening consequences; Grade 5: death related to AE. Higher grade indicates greater severity. An increase is defined as an increase in CTCAE grade relative to Baseline grade. Baseline was the most recent, non-missing value prior to or on the first study treatment dose date. Data for worst-case post Baseline with any grade increase is presented.

End point type	Secondary
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End point timeframe:

Up to 36.4 weeks

Notes:

[501] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[502]	16 ^[503]	1 ^[504]	
Units: Participants				
Hemoglobin	4	8	1	
Lymphocytes	4	8	1	
Neutrophils	2	7	0	
Platelets	5	9	1	
Leukocytes	1	6	0	

Notes:

[502] - All Treated Population

[503] - All Treated Population

[504] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with worst-case urinalysis results post-Baseline relative to Baseline by dipstick method

End point title	Part 2: Number of participants with worst-case urinalysis results post-Baseline relative to Baseline by dipstick method ^[505]
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End point description:

Urine samples were collected to assess glucose, ketones, occult blood, urine protein. The dipstick test gave results in a semi-quantitative manner, and results for urinalysis parameters were recorded as negative, trace, 1+, 2+, 3+ indicating proportional concentrations in the urine sample. Any increase was defined as any increase in proportional concentrations relative to Baseline. Baseline was the most recent, non-missing value prior to or on the first study treatment dose date. Data for worst-case post Baseline with any increase is presented. Only those participants with data available at the specified data points were analyzed represented by n=X in category titles).

End point type	Secondary
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End point timeframe:

Up to 36.4 weeks

Notes:

[505] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[506]	12 ^[507]	1 ^[508]	
Units: Participants				
Glucose, n=5,12,1	4	3	0	
Ketones, n=7,12,1	1	0	0	
Occult blood, n=7,8,1	2	2	0	
Protein, n=6,11,1	0	7	0	

Notes:

[506] - All Treated Population

[507] - All Treated Population

[508] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with worst case vital signs results relative to Baseline: Pulse rate and body temperature

End point title	Part 2: Number of participants with worst case vital signs results relative to Baseline: Pulse rate and body temperature ^[509]
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End point description:

Vital signs (pulse rate and temperature) were measured after resting for at least 5 minutes in a supine or semi-recumbent position. The clinical concern ranges were: For pulse rate (low <60 beats per minute [bpm] and high >100 bpm); For body temperature (<=35 degrees Celsius or >=38 degrees Celsius). Participants were counted in the worst case category that their value changed to (low, normal or high), unless there was no change in their category. Participants whose value category was unchanged, or whose value became normal, were recorded in the "To Normal or No Change" category. Participants were counted twice if the participant had values that changed "To Low" and "To High", so the percentages may not add to 100%. Baseline was the most recent, non-missing value prior to or on the first study treatment dose date.

End point type	Secondary
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End point timeframe:

Up to 36.4 weeks

Notes:

[509] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[510]	16 ^[511]	1 ^[512]	
Units: Participants				
Pulse rate, To Low	2	0	0	

Pulse rate, To Normal or No change	3	9	0	
Pulse Rate, To High	3	7	1	
Temperature, To Low	1	0	0	
Temperature, To Normal or No Change	5	13	1	
Temperature, To High	1	3	0	

Notes:

[510] - All Treated Population

[511] - All Treated Population

[512] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with increase to Grade 3 from Baseline in vital signs: DBP and SBP

End point title	Part 2: Number of participants with increase to Grade 3 from Baseline in vital signs: DBP and SBP ^[513]
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End point description:

DBP and SBP were measured after resting for at least 5 minutes in a supine or semi-recumbent position. They were graded according to NCI-CTCAE version 4.0. For SBP: Grade 0 (≤ 120 millimeter of mercury [mmHg]), Grade 1 (121-139 mmHg), Grade 2 (140-159 mmHg), Grade 3 (≥ 160 mmHg). For DBP: Grade 0 (≤ 80 mmHg), Grade 1 (81-89 mmHg), Grade 2 (90-99 mmHg), Grade 3 (≥ 100 mmHg). Higher grade indicates greater severity. Baseline was the most recent, non-missing value prior to or on the first study treatment dose date. An increase is defined as an increase in grade relative to Baseline grade. Number of participants with increase to Grade 3 from Baseline is presented.

End point type	Secondary
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End point timeframe:

Up to 36.4 weeks

Notes:

[513] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[514]	16 ^[515]	1 ^[516]	
Units: Participants				
DBP	0	0	0	
SBP	3	1	1	

Notes:

[514] - All Treated Population

[515] - All Treated Population

[516] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of participants with worst-case post-Baseline abnormal electrocardiogram (ECG) findings (investigator reading)

End point title	Part 2: Number of participants with worst-case post-Baseline
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End point description:

12-lead ECGs were recorded with the participants in a supine position using an ECG machine. Number of participants with worst-case clinically significant and not clinically significant abnormal ECG findings have been presented. Clinically significant abnormal findings are those which are not associated with the underlying disease, unless judged by the investigator to be more severe than expected for the participant's condition.

End point type Secondary

End point timeframe:

Up to 36.4 weeks

Notes:

[517] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[518]	16 ^[519]	1 ^[520]	
Units: Participants				
Abnormal-Clinically significant	0	1	0	
Abnormal-Not Clinically significant	6	11	1	

Notes:

[518] - All Treated Population

[519] - All Treated Population

[520] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Progression free survival (PFS)

End point title Part 2: Progression free survival (PFS)^[521]

End point description:

PFS is interval of time(in months)between date of first dose &earlier of date of disease progression &date of death due to any cause. Progression is participants(pt's)with MDS &with<5% blasts:>=50% increase in blastto>5% blasts/pt's with 5-10% blasts:>=50% increase to >10% blast pt's with 10-20% blast:>=50%increase to >20% blast, pt's with 20%-30% blast:>=50% increase to>30% blast, For CTCL:>=25% increase in skin disease from Baseline/new tumor(T3[1/more tumors(>=1cm diameter)]) in pt's with T1(Limited patches,papule&/or plaque covering<10% of skin surface;may stratify in T1a[patch only]v T1b [plaque+-patch]),T2(Patch,papule/plaque covering >=10% of skin surface;may stratify in T2a[patch only]v T2b [plaque+-patch])/T4(Confluence of erythema covering >=80% body surface area)only skin disease/loss of response in pts with CR/PR,increase of skin score of >sum of nadir +50% Baseline score.55555-median &IQR range could not be calculated.

End point type Secondary

End point timeframe:

Up to 36.4 weeks

Notes:

[521] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[522]	16 ^[523]	1 ^[524]	
Units: Months				
median (inter-quartile range (Q1-Q3))	8.15 (3.48 to 55555)	2.00 (1.45 to 3.48)	55555 (55555 to 55555)	

Notes:

[522] - All Treated Population

[523] - All Treated Population

[524] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Duration of response (DOR)

End point title	Part 2: Duration of response (DOR) ^[525]
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End point description:

Duration of response is defined as the time from the first documented evidence response (CR or PR lasting 4 months for CTCL; and CR, marrow CR, CRp, Cri or PR for MDS) until the first documented disease progression or death due to any cause. Median and inter-quartile range (first quartile and third quartile) of duration of response are presented. Only those participants with data available at the specified data points were analyzed. Participants with incomplete response rates were excluded from the analysis.

End point type	Secondary
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End point timeframe:

Up to 36.4 weeks

Notes:

[525] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 75 mg QD MDS			
Subject group type	Reporting group			
Number of subjects analysed	4 ^[526]			
Units: Months				
median (inter-quartile range (Q1-Q3))	3.29 (3.29 to 3.29)			

Notes:

[526] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Overall survival (OS)

End point title	Part 2: Overall survival (OS) ^[527]
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End point description:

OS is defined as the interval of time (in months) between the date of first dose and the date of death due to any cause. Median and inter-quartile range (first quartile and third quartile) of overall survival

are presented. 55555 indicates median and inter-quartile range could not be calculated.

End point type	Secondary
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End point timeframe:

Up to 36.4 weeks

Notes:

[527] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is only reporting on a subset of the arms that are contained in the baseline period

End point values	Part 2: GSK525762 60 mg QD CTCL	Part 2: GSK525762 75 mg QD MDS	Part 2: GSK525762 80 mg QD CTCL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[528]	16 ^[529]	1 ^[530]	
Units: Months				
median (inter-quartile range (Q1-Q3))	55555 (55555 to 55555)	5.85 (1.46 to 16.10)	55555 (55555 to 55555)	

Notes:

[528] - All Treated Population

[529] - All Treated Population

[530] - All Treated Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality, non-serious and serious adverse events were collected from the start of study treatment until 28 days following discontinuation of study treatment (up to 86.9 weeks for Part 1 and up to 36.4 weeks for Part 2)

Adverse event reporting additional description:

All-cause mortality, non-serious and serious adverse events were collected in All Treated population.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	GSK525762 5 MG QD
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Reporting group description:

Participants were administered once daily oral dose of 5 milligrams (mg) GSK525762.

Reporting group title	GSK525762 10 MG QD
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Reporting group description:

Participants were administered once daily oral dose of 10 mg GSK525762.

Reporting group title	GSK525762 20 MG QD
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Reporting group description:

Participants were administered once daily oral dose of 20 mg GSK525762.

Reporting group title	GSK525762 30 MG QD MM
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Reporting group description:

Participants with multiple myeloma (MM) were administered once daily oral dose of 30 mg GSK525762.

Reporting group title	GSK525762 40 MG QD
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Reporting group description:

Participants were administered once daily oral dose of 40 mg GSK525762.

Reporting group title	GSK525762 40 MG QD MM
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Reporting group description:

Participants with MM were administered once daily oral dose of 40 mg GSK525762.

Reporting group title	GSK525762 60 MG QD AML
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Reporting group description:

Participants with Acute Myeloid Leukemia (AML) were administered once daily oral dose of 60 mg GSK525762.

Reporting group title	GSK525762 60 MG QD NHL
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Reporting group description:

Participants with Non-Hodgkin's Lymphoma (NHL) were administered once daily oral dose of 60 mg GSK525762.

Reporting group title	GSK525762 60 MG QD MM
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Reporting group description:

Participants with MM were administered once daily oral dose of 60 mg GSK525762.

Reporting group title	GSK525762 75 MG QD AML
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Reporting group description:

Participants with AML were administered once daily oral dose of 75 mg GSK525762.

Reporting group title	GSK525762 80 MG QD
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Reporting group description:

Participants were administered once daily oral dose of 80 mg GSK525762.

Reporting group title	GSK525762 80 MG QD AML
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Reporting group description:

Participants with AML were administered once daily oral dose of 80 mg GSK525762.

Reporting group title	GSK525762 80 MG QD NHL
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Reporting group description:

Participants with NHL were administered once daily oral dose of 80 mg GSK525762.

Reporting group title	GSK525762 100 MG QD AML
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Reporting group description:

Participants with AML were administered once daily oral dose of 100 mg GSK525762.

Reporting group title	GSK525762 120 MG QD AML
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Reporting group description:

Participants with AML were administered once daily oral dose of 120 mg GSK525762.

Reporting group title	GSK525762 60 MG QD CTCL
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Reporting group description:

Participants Cutaneous T cell lymphoma (CTCL) were administered once daily oral dose of 60 mg GSK525762.

Reporting group title	GSK525762 75 MG QD MDS
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Reporting group description:

Participants with Myelodysplastic Syndrome (MDS) were administered once daily oral dose of 75 mg GSK525762.

Reporting group title	GSK525762 80 MG QD CTCL
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Reporting group description:

Participants CTCL were administered once daily oral dose of 80 mg GSK525762.

Serious adverse events	GSK525762 5 MG QD	GSK525762 10 MG QD	GSK525762 20 MG QD
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chloroma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Humerus fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			

Haemorrhage intracranial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperammonaemic encephalopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial haematoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bacterial sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex reactivation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucormycosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster virus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation ketoacidosis			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK525762 30 MG QD MM	GSK525762 40 MG QD	GSK525762 40 MG QD MM
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 5 (80.00%)	0 / 1 (0.00%)	3 / 4 (75.00%)
number of deaths (all causes)	4	0	3
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chloroma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleural effusion			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcus test positive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infusion related reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Haemorrhage intracranial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperammonaemic encephalopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cellulitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex reactivation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucormycosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster virus infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation ketoacidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK525762 60 MG QD AML	GSK525762 60 MG QD NHL	GSK525762 60 MG QD MM
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 8 (75.00%)	12 / 18 (66.67%)	2 / 3 (66.67%)
number of deaths (all causes)	7	12	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chloroma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	1 / 8 (12.50%)	2 / 18 (11.11%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ejection fraction decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcus test positive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Road traffic accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Haemorrhage intracranial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyperammonaemic encephalopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	8 / 18 (44.44%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	8 / 9	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	2 / 8 (25.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	2 / 8 (25.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Anaemia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			

subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 8 (12.50%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex reactivation			

subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Mucormycosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster virus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			

subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation ketoacidosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Serious adverse events	GSK525762 75 MG	GSK525762 80 MG	GSK525762 80 MG
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	QD AML	QD	QD AML
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	1 / 1 (100.00%)	6 / 7 (85.71%)
number of deaths (all causes)	8	1	7
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chloroma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haemothorax			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Staphylococcus test positive subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Rib fracture subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Transfusion reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Haemorrhage intracranial			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperammonaemic encephalopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intracranial haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	3 / 8 (37.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	3 / 7 (42.86%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Chalazion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 1 (100.00%)	3 / 7 (42.86%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex reactivation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucormycosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster virus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation ketoacidosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK525762 80 MG QD NHL	GSK525762 100 MG QD AML	GSK525762 120 MG QD AML
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	14 / 16 (87.50%)	6 / 6 (100.00%)
number of deaths (all causes)	6	15	6
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chloroma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			

subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcus test positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Troponin I increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Rib fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Upper limb fracture subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Haemorrhage intracranial subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cerebrovascular accident subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperammonaemic encephalopathy subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial haematoma subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Spinal cord compression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	5 / 7 (71.43%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	5 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	3 / 6 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	2 / 7 (28.57%)	5 / 16 (31.25%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 2	1 / 11	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	4 / 16 (25.00%)	2 / 6 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			

subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex reactivation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucormycosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster virus infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation ketoacidosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK525762 60 MG QD CTCL	GSK525762 75 MG QD MDS	GSK525762 80 MG QD CTCL
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 7 (71.43%)	12 / 16 (75.00%)	1 / 1 (100.00%)
number of deaths (all causes)	1	13	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chloroma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Anaphylactic reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcus test positive			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural			

complications			
Rib fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Haemorrhage intracranial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperammonaemic encephalopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial haematoma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 16 (25.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	4 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	1 / 1 (100.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gingival hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctalgia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic sepsis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 7 (14.29%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex reactivation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 7 (14.29%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucormycosis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster virus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Starvation ketoacidosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour lysis syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	GSK525762 5 MG QD	GSK525762 10 MG QD	GSK525762 20 MG QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	1 / 1 (100.00%)	1 / 1 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 1 (100.00%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anxiety			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	2
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry mouth			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	1 / 1 (100.00%) 1 0 / 1 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) Muscle spasms subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all) Oral herpes subjects affected / exposed occurrences (all) Upper respiratory tract infection	1 / 1 (100.00%) 1 0 / 1 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0

subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	GSK525762 30 MG QD MM	GSK525762 40 MG QD	GSK525762 40 MG QD MM
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	1 / 1 (100.00%)	4 / 4 (100.00%)
Vascular disorders			

Hypotension subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1
Hypertension subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 2	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 2	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1
Asthenia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Mucosal inflammation subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 2	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	1 / 1 (100.00%) 1	0 / 4 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Oropharyngeal pain			

subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 1 (100.00%) 1	0 / 4 (0.00%) 0
Psychiatric disorders Confusional state subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Investigations Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
International normalised ratio increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1
Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Cardiac disorders Angina pectoris subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Nervous system disorders Dysgeusia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	3 / 4 (75.00%)
occurrences (all)	1	0	3
Anaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Febrile neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	5
Coagulopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 5 (40.00%)	1 / 1 (100.00%)	1 / 4 (25.00%)
occurrences (all)	2	2	2
Nausea			

subjects affected / exposed	2 / 5 (40.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 5 (0.00%)	1 / 1 (100.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Myalgia subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Infections and infestations			
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 5 (40.00%) 2	1 / 1 (100.00%) 1	0 / 4 (0.00%) 0
Lower respiratory tract infection subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	1 / 1 (100.00%) 1	0 / 4 (0.00%) 0
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 5 (0.00%) 0	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Metabolism and nutrition disorders			
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1
Decreased appetite subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 1 (0.00%) 0	1 / 4 (25.00%) 1
Hypomagnesaemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	1 / 5 (20.00%) 1	0 / 1 (0.00%) 0	0 / 4 (0.00%) 0
Hypoalbuminaemia			

subjects affected / exposed	1 / 5 (20.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 1 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	GSK525762 60 MG QD AML	GSK525762 60 MG QD NHL	GSK525762 60 MG QD MM
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	18 / 18 (100.00%)	3 / 3 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 8 (12.50%)	6 / 18 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	6	1
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 18 (16.67%)	2 / 3 (66.67%)
occurrences (all)	0	5	2
Asthenia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 18 (11.11%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Oedema peripheral			
subjects affected / exposed	1 / 8 (12.50%)	2 / 18 (11.11%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Mucosal inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	1 / 18 (5.56%) 1	1 / 3 (33.33%) 1
Epistaxis subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	2 / 18 (11.11%) 2	1 / 3 (33.33%) 1
Dyspnoea subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	2 / 18 (11.11%) 2	1 / 3 (33.33%) 1
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	2 / 18 (11.11%) 2	0 / 3 (0.00%) 0
Psychiatric disorders Confusional state subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0
Investigations Blood bilirubin increased subjects affected / exposed occurrences (all)	3 / 8 (37.50%) 4	3 / 18 (16.67%) 4	0 / 3 (0.00%) 0
International normalised ratio increased subjects affected / exposed occurrences (all)	3 / 8 (37.50%) 4	2 / 18 (11.11%) 2	0 / 3 (0.00%) 0
Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	5 / 18 (27.78%) 5	0 / 3 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	0 / 18 (0.00%) 0	1 / 3 (33.33%) 1
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0

Weight decreased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0
Cardiac disorders Angina pectoris subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0
Nervous system disorders Dysgeusia subjects affected / exposed occurrences (all)	3 / 8 (37.50%) 3	2 / 18 (11.11%) 2	0 / 3 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 18 (5.56%) 1	1 / 3 (33.33%) 1
Headache subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0
Taste disorder subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0
Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	8 / 18 (44.44%) 8	1 / 3 (33.33%) 1
Anaemia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	6 / 18 (33.33%) 6	1 / 3 (33.33%) 1
Febrile neutropenia subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	3 / 18 (16.67%) 4	0 / 3 (0.00%) 0
Coagulopathy			

subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 18 (0.00%) 0	0 / 3 (0.00%) 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 8 (37.50%)	7 / 18 (38.89%)	0 / 3 (0.00%)
occurrences (all)	6	8	0
Nausea			
subjects affected / exposed	3 / 8 (37.50%)	6 / 18 (33.33%)	2 / 3 (66.67%)
occurrences (all)	4	7	2
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)	3 / 18 (16.67%)	2 / 3 (66.67%)
occurrences (all)	1	3	3
Abdominal pain			
subjects affected / exposed	2 / 8 (25.00%)	3 / 18 (16.67%)	2 / 3 (66.67%)
occurrences (all)	2	4	2
Constipation			
subjects affected / exposed	2 / 8 (25.00%)	2 / 18 (11.11%)	1 / 3 (33.33%)
occurrences (all)	2	2	1
Dry mouth			
subjects affected / exposed	1 / 8 (12.50%)	3 / 18 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 8 (12.50%)	3 / 18 (16.67%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue			

disorders			
Back pain			
subjects affected / exposed	1 / 8 (12.50%)	1 / 18 (5.56%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Muscle spasms			
subjects affected / exposed	2 / 8 (25.00%)	2 / 18 (11.11%)	1 / 3 (33.33%)
occurrences (all)	2	2	1
Myalgia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 8 (12.50%)	1 / 18 (5.56%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Decreased appetite			
subjects affected / exposed	2 / 8 (25.00%)	3 / 18 (16.67%)	2 / 3 (66.67%)
occurrences (all)	2	3	2
Hypokalaemia			
subjects affected / exposed	3 / 8 (37.50%)	1 / 18 (5.56%)	1 / 3 (33.33%)
occurrences (all)	3	1	1
Hypomagnesaemia			

subjects affected / exposed	1 / 8 (12.50%)	1 / 18 (5.56%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Hyponatraemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 18 (5.56%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 18 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	GSK525762 75 MG QD AML	GSK525762 80 MG QD	GSK525762 80 MG QD AML
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	1 / 1 (100.00%)	7 / 7 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	1 / 1 (100.00%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 1 (100.00%)	3 / 7 (42.86%)
occurrences (all)	0	1	3
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	3 / 7 (42.86%)
occurrences (all)	1	0	3
Pyrexia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Asthenia			
subjects affected / exposed	3 / 8 (37.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Oedema peripheral			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Mucosal inflammation			

subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	4
Dyspnoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Investigations			
Blood bilirubin increased			
subjects affected / exposed	4 / 8 (50.00%)	1 / 1 (100.00%)	3 / 7 (42.86%)
occurrences (all)	4	1	3
International normalised ratio increased			
subjects affected / exposed	2 / 8 (25.00%)	0 / 1 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 8 (12.50%)	1 / 1 (100.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 1 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 1 (100.00%) 1	0 / 7 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Cardiac disorders Angina pectoris subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Nervous system disorders Dysgeusia subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	0 / 1 (0.00%) 0	3 / 7 (42.86%) 3
Dizziness subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Taste disorder subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Blood and lymphatic system disorders Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	1 / 1 (100.00%) 1	1 / 7 (14.29%) 1

Febrile neutropenia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Coagulopathy subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	1 / 7 (14.29%) 1
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	4 / 8 (50.00%) 4	1 / 1 (100.00%) 2	4 / 7 (57.14%) 6
Nausea subjects affected / exposed occurrences (all)	4 / 8 (50.00%) 4	0 / 1 (0.00%) 0	6 / 7 (85.71%) 6
Vomiting subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	1 / 1 (100.00%) 1	2 / 7 (28.57%) 2
Abdominal pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	1 / 7 (14.29%) 1
Constipation subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	1 / 1 (100.00%) 1	0 / 7 (0.00%) 0
Dry mouth subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Hepatobiliary disorders			
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	3 / 8 (37.50%) 3	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Skin and subcutaneous tissue disorders			
Rash subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	0 / 1 (0.00%) 0	1 / 7 (14.29%) 1
Pruritus			

subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0	0 / 1 (0.00%) 0	0 / 7 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) Muscle spasms subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	1 / 7 (14.29%) 1 0 / 7 (0.00%) 0 1 / 7 (14.29%) 1
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all) Oral herpes subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Lower respiratory tract infection subjects affected / exposed occurrences (all) Oral candidiasis subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0 0 / 8 (0.00%) 0 1 / 8 (12.50%) 1 0 / 8 (0.00%) 0 0 / 8 (0.00%) 0	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0	1 / 7 (14.29%) 1 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0 0 / 7 (0.00%) 0
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	0 / 1 (0.00%) 0	1 / 7 (14.29%) 1

Decreased appetite subjects affected / exposed occurrences (all)	3 / 8 (37.50%) 3	0 / 1 (0.00%) 0	2 / 7 (28.57%) 2
Hypokalaemia subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	1 / 1 (100.00%) 3	1 / 7 (14.29%) 1
Hypomagnesaemia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	1 / 1 (100.00%) 1	1 / 7 (14.29%) 1
Hyponatraemia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	1 / 1 (100.00%) 1	0 / 7 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2	1 / 1 (100.00%) 2	0 / 7 (0.00%) 0
Hypophosphataemia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1	1 / 1 (100.00%) 1	0 / 7 (0.00%) 0

Non-serious adverse events	GSK525762 80 MG QD NHL	GSK525762 100 MG QD AML	GSK525762 120 MG QD AML
Total subjects affected by non-serious adverse events subjects affected / exposed	7 / 7 (100.00%)	16 / 16 (100.00%)	6 / 6 (100.00%)
Vascular disorders			
Hypotension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 16 (6.25%) 1	0 / 6 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	4 / 16 (25.00%) 4	1 / 6 (16.67%) 1
Pyrexia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	3 / 16 (18.75%) 3	2 / 6 (33.33%) 2

Asthenia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	2 / 6 (33.33%)
occurrences (all)	0	2	2
Mucosal inflammation			
subjects affected / exposed	1 / 7 (14.29%)	2 / 16 (12.50%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 7 (14.29%)	3 / 16 (18.75%)	0 / 6 (0.00%)
occurrences (all)	1	4	0
Epistaxis			
subjects affected / exposed	1 / 7 (14.29%)	2 / 16 (12.50%)	1 / 6 (16.67%)
occurrences (all)	1	2	2
Dyspnoea			
subjects affected / exposed	1 / 7 (14.29%)	2 / 16 (12.50%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)	11 / 16 (68.75%)	3 / 6 (50.00%)
occurrences (all)	0	11	3
International normalised ratio increased			
subjects affected / exposed	0 / 7 (0.00%)	8 / 16 (50.00%)	3 / 6 (50.00%)
occurrences (all)	0	10	3

Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 7 (0.00%)	4 / 16 (25.00%)	2 / 6 (33.33%)
occurrences (all)	0	4	2
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 16 (6.25%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dysgeusia			
subjects affected / exposed	1 / 7 (14.29%)	6 / 16 (37.50%)	1 / 6 (16.67%)
occurrences (all)	1	6	1
Dizziness			
subjects affected / exposed	1 / 7 (14.29%)	3 / 16 (18.75%)	1 / 6 (16.67%)
occurrences (all)	1	3	1
Headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Thrombocytopenia subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	1 / 16 (6.25%) 1	0 / 6 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 4	2 / 16 (12.50%) 2	0 / 6 (0.00%) 0
Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 6 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Coagulopathy subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	1 / 6 (16.67%) 1
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	11 / 16 (68.75%) 15	3 / 6 (50.00%) 3
Nausea subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	8 / 16 (50.00%) 10	3 / 6 (50.00%) 4
Vomiting subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	4 / 16 (25.00%) 4	1 / 6 (16.67%) 1
Abdominal pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	3 / 16 (18.75%) 3	1 / 6 (16.67%) 1
Constipation subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	3 / 16 (18.75%) 3	0 / 6 (0.00%) 0
Dry mouth subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Hepatobiliary disorders			

Hyperbilirubinaemia subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 2	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	2 / 16 (12.50%) 2	0 / 6 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	3 / 16 (18.75%) 3	1 / 6 (16.67%) 1
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 16 (6.25%) 1	0 / 6 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 6 (0.00%) 0
Infections and infestations Urinary tract infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 16 (6.25%) 1	1 / 6 (16.67%) 1
Oral herpes subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Lower respiratory tract infection			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Metabolism and nutrition disorders			
Hyperglycaemia subjects affected / exposed occurrences (all)	4 / 7 (57.14%) 8	7 / 16 (43.75%) 7	3 / 6 (50.00%) 3
Decreased appetite subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	3 / 16 (18.75%) 3	1 / 6 (16.67%) 1
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	4 / 16 (25.00%) 6	3 / 6 (50.00%) 3
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 6 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 6 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 6 (0.00%) 0
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	1 / 6 (16.67%) 1

Non-serious adverse events	GSK525762 60 MG QD CTCL	GSK525762 75 MG QD MDS	GSK525762 80 MG QD CTCL
Total subjects affected by non-serious adverse events subjects affected / exposed	7 / 7 (100.00%)	16 / 16 (100.00%)	1 / 1 (100.00%)
Vascular disorders			
Hypotension subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 1 (0.00%) 0
Hypertension			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 1 (0.00%) 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	4 / 7 (57.14%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	4	1	0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 16 (6.25%)	1 / 1 (100.00%)
occurrences (all)	1	1	1
Oedema peripheral			
subjects affected / exposed	1 / 7 (14.29%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 7 (14.29%)	2 / 16 (12.50%)	1 / 1 (100.00%)
occurrences (all)	1	2	1
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Confusional state subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 1 (0.00%) 0
Investigations			
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 3	0 / 1 (0.00%) 0
International normalised ratio increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 1 (0.00%) 0
Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 1 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 1 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 1 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	2 / 16 (12.50%) 2	0 / 1 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 16 (6.25%) 1	0 / 1 (0.00%) 0
Cardiac disorders			
Angina pectoris subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 1 (0.00%) 0
Nervous system disorders			
Dysgeusia subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 4	6 / 16 (37.50%) 6	1 / 1 (100.00%) 1
Dizziness			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	3 / 16 (18.75%) 3	0 / 1 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 1 (0.00%) 0
Taste disorder subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	0 / 1 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	1 / 16 (6.25%) 1	0 / 1 (0.00%) 0
Blood and lymphatic system disorders			
Thrombocytopenia subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 5	1 / 16 (6.25%) 1	1 / 1 (100.00%) 2
Anaemia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 16 (12.50%) 2	1 / 1 (100.00%) 2
Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 1 (0.00%) 0
Neutropenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 1 (0.00%) 0
Coagulopathy subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 16 (0.00%) 0	0 / 1 (0.00%) 0
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	11 / 16 (68.75%) 14	0 / 1 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	11 / 16 (68.75%) 12	0 / 1 (0.00%) 0
Vomiting			

subjects affected / exposed	2 / 7 (28.57%)	7 / 16 (43.75%)	0 / 1 (0.00%)
occurrences (all)	2	8	0
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	4 / 16 (25.00%)	0 / 1 (0.00%)
occurrences (all)	0	5	0
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Dry mouth			
subjects affected / exposed	2 / 7 (28.57%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	4	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 7 (0.00%)	3 / 16 (18.75%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Pruritus			
subjects affected / exposed	1 / 7 (14.29%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	3 / 16 (18.75%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Infections and infestations			
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	3 / 16 (18.75%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Oral candidiasis			
subjects affected / exposed	1 / 7 (14.29%)	1 / 16 (6.25%)	0 / 1 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	2 / 7 (28.57%)	3 / 16 (18.75%)	0 / 1 (0.00%)
occurrences (all)	2	3	0
Decreased appetite			
subjects affected / exposed	2 / 7 (28.57%)	4 / 16 (25.00%)	0 / 1 (0.00%)
occurrences (all)	2	4	0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	3	0
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 16 (12.50%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 16 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 August 2013	Amendment 1: The study duration has been modified at the request of the Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom. MHRA requested the removal of "until commercial supply of GSK525762 becomes available" as a duration of exposure in accordance with the Commission Directive 2005/28/EC. In addition, the sponsor/medical monitor information page has updated information.
15 October 2013	Amendment 2: At the request of the Food and Drug Administration (FDA), United States, the dose limiting toxicity (DLT) was updated to require that it must clearly be established that an event is unrelated to treatment for the event to not be considered a DLT; the stopping rules related to safety were expanded. Additional changes include the clarification of exploratory endpoints to assess metabolites, correction of exclusion criteria and clarification of the Time and Events Table, Dietary Restrictions, and the futility analysis of Part 2.
12 November 2014	Amendment 3: The secondary objectives of Part 1 were updated to include evaluation of the clinical activity of GSK525762 (response rate and overall survival). Additional details of twice daily (BID) dosing during dose escalation were included. Eligibility criteria refined: 1) Clarification of eligibility for participants with Acute Myeloid Leukemia (AML) (Part 1 and 2). Platelets count eligibility criteria were specified for each group of hematological malignancies separately. 3) Exemption of exclusion due to prior allogeneic stem cell transplant added. DLT for hematological toxicities clarified and dose reduction algorithm for thrombocytopenia added. Study statistic amended for part 2 (AML expansion cohort): hypothesis and number of participants. Data from ongoing preclinical and clinical research added. Time point of collection for samples for disease and efficacy assessments refined. List of baseline assessments for each indication added. Minor clarifications, reformatting of tables and typographical errors are also addressed in this amendment.
06 April 2015	Amendment 4: An update to the corrected QT(QTc) management guidelines and enhanced guidance for management and dose modifications for thrombocytopenia, specifically for participants with AML, has been added. Separation of cohorts in Part 1 was included to determine Maximum tolerated dose (MTD)/ Recommended Part 2 Dose (RP2D) separately in AML, Multiple Myeloma (MM), Non-Hodgkin's Lymphoma (NHL) cohorts. Eligibility criteria were refined to account for new platelet management guidelines. Eligibility regarding prior allogeneic stem cell transplant and central nervous system (CNS) disease were simplified. Inclusion of dose expansion cohorts for MM and NHL has been added in Part 2. PD assessments have been removed from Part 2 and tumor biopsies were added in Part 2 for translational research. The 100 milligrams (mg) dose strength was removed due to a change in manufacturing. Minor clarifications, reformatting of tables and typographical errors were also addressed in this amendment.
08 July 2015	Amendment 5: Updated inclusion criteria and guidance on contraception use based on emerging data from preclinical studies of embryo-fetal development. Minor clarifications were made regarding the Echo and Holter monitoring requirements and the list of medications with risk for Torsades de Pointes and prohibited medications were updated. The AML response criteria were updated with modified Cheson 2003 guidelines. Furthermore, the dosing schedule was updated to a continuous daily dosing schedule. Finally, after an internal QTc analysis and evaluation of cardiac safety data collected from all participants in the BET115521 (NCT01587703) study up to and including the 100mg Once daily (QD) cohort available by 15-May-2015, the 48-hour telemetry requirement has been removed for all parts of the study and the frequency of Holter Monitoring was decreased in Part 1. Minor clarifications, reformatting of tables and typographical errors were also addressed in this amendment.

15 March 2016	Amendment 6: Updated Visit Windows to provide additional clarification on clinical visits. Updated GSK525762 Investigational Product Dosage/Administration to include both amorphous free base and crystalline besylate formulations of GSK525762 in the study. Updated Meals and Dietary Restrictions to include the meals and dietary requirements for the new besylate formulation included in the study. Minor clarifications, reformatting of tables and typographical errors were also addressed in this amendment.
23 June 2016	Amendment 7: Study design was amended to include collection of additional safety data of GSK525762 twice daily (BID) dosing (exploratory cohort) after determination of maximum tolerated dose with QD dose and to evaluate the preliminary efficacy of GSK525762 BID dosing. The secondary objectives of Part 1 were updated to include evaluation of clinical efficacy of GSK525762 (overall response rate). The endpoints for secondary objective of Part 2 (determination of clinical activity of GSK525762) was updated to include Time to Progression (TTP), Duration of Response (DOR), progression Free Survival (PFS) for MM and NHL. Eligibility criteria were clarified specifying hematologic malignancies (AML, MM, NHL) for both Part 1 and 2. Risk associated with drug interaction was updated. Permanent discontinuation from study treatment section was updated. Time and events tables were also updated in line with study design modifications. Whole section of urine collection was removed. Tables of cautionary medications, prohibited medications and drugs affecting pharmacokinetic (PK) of GSK525762 were updated. Interim analysis was included for part 1. Minor clarifications, formatting and typographical errors were also addressed in this amendment.
14 February 2017	Amendment 8: The study population for the AML cohort in Part 2 was amended from a population of participants with AML to a population of participants with relapsed or refractory myelodysplastic syndrome (MDS) or hypoproliferative AML that has arisen from an antecedent MDS. The Part 2 primary and secondary objectives along with the eligibility criteria were updated to include this new population. The safety assessments were updated to be in line with the Investigator Brochure. The dose limiting toxicity criteria were modified to remove the specific criteria for leukemia. The time and events tables were updated to reduce the cardiac monitoring (ecg, holter and troponin), remove Messenger Ribonucleic acid (mRNA) and cytokine collection, add a Pain Assessment, addition of an exploratory translational research blood draw and to add Factor VII assay collection. The disease related events/outcomes section was removed and the pregnancy reporting timeframe was reduced to 24 hours. Fever was removed from the dose adjusting/stopping safety criteria. Aspirin and non-steroidal-anti-inflammatory drugs (NSAIDs) were added to the Cautionary medications. Response Criteria for Myelodysplastic Syndromes (MDS) was added as an Appendix. GlaxoSmithKline Document Number 2011N113741_03 Version 3 changed to GlaxoSmithKline Document Number 2011N113741_05 Version 5 throughout the document. Table numbers were updated. Figure numbers are updated throughout the document. Minor clarifications, formatting and typographical errors were also addressed in this amendment.
15 March 2018	Amendment 9: The study population for the NHL cohort in Part 2 was amended from a population of participants with NHL to a population of participants with cutaneous T-cell lymphoma (CTCL). The Part 2 primary and secondary objectives along with the eligibility criteria were updated to include this new CTCL population, and removal of expansion into multiple myeloma in Part 2. Eligibility criteria for all populations were updated (ECOG, cardiac safety). The time and events tables were updated to reduce the cardiac monitoring based on updated risk/benefit profile, and BID dosing was removed. Medications affecting QT prolongation were re-categorized from prohibited to cautionary. Liver chemistry monitoring, interruption stopping and follow-up criteria were updated as per latest criteria. Response Criteria for CTCL was added as an Appendix, and a QOL questionnaire (SKINDEX-29) was added. Minor clarifications, formatting and typographical errors were also addressed in this amendment.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported