Clinical trial results:
A Phase I/II study to assess the safety and immunogenicity of recMAGE-A3+AS15 cancer immunotherapeutic given as adjuvant therapy, with or without standard adjuvant chemo(-radio)therapy, to patients with MAGE A3-positive Non-Small Cell Lung Cancer (stage IB, II or III).

Summary

EudraCT number	2006-004777-10
Trial protocol	GB BE DE FR IT
Global end of trial date	08 August 2013

Results information

Result version number	v1
This version publication date	11 May 2016
First version publication date	13 June 2015

Trial information

Trial identification

Sponsor protocol code	107240

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00455572
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, 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	05 June 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 August 2013
Global end of trial reached?	Yes
Global end of trial date	08 August 2013
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the humoral and cellular immune response induced by recMAGE-A3+AS15 in patients with MAGE-A3-positive Non-Small Cell Lung Cancer (NSCLC). • To evaluate the safety of recMAGE-A3+AS15 in patients with MAGE-A3-positive NSCLC.

Protection of trial subjects:

All subjects were supervised after MAGE-A3 ASCI study product administration with appropriate medical treatment readily available. The MAGE-A3 ASCI study product was administered by qualified and trained personnel, and only to eligible patients who had no contraindications to any components of the MAGE-A3 ASCI study product. Subjects were followed up for occurrences of adverse events (AEs), including abnormal hematological and biochemical laboratory values, potential immune-mediated disorders (pIMDs and serious adverse events (SAEs) during the entire study period study. For subjects in all groups, if during the study the investigator was to come to consider any deviation from protocol-defined rules as to be in the patient's interest, then the investigator's decision was given priority over the rules. For Cohort 4, the chemo- and radiotherapy regimen was based upon the site's own standard procedures; again, the choice of treatment and any modification of this was to be governed by considerations of the patient's interest. Chemo- and radiotherapy may be administered in either sequence or concurrently. All patients who withdrew from the study and who had received any dose of study treatment were encouraged to be followed for assessment of possible toxicity. These patients were to be examined not less than 30 days and not more than 37 days after the last administration of MAGE-A3 ASCI study product.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 May 2007
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	United Kingdom: 8
Country: Number of subjects enrolled	Belgium: 15
Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Italy: 11
Country: Number of subjects enrolled	Canada: 3
Worldwide total number of subjects	70
EEA total number of subjects	67

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)	35
From 65 to 84 years	35
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

70 patients were screened towards participation in the study. Out of these 70 patients, 67 were assessed as eligible for treatment and were administered the study MAGE-A3 ASCI study treatment.

Period 1

Period 1 title	Overall Study Period (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Chemotherapy + MAGE-A3 ASCI Group

Arm description:

This group (Cohort 1 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors, who are due for chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product concurrently with cis-diaminedichloroplatine (CDDP) + vinorelbine [either Vinorelbine or Pierre Fabre's Navelbine] chemotherapy. The 8-dose course of MAGE-A3 ASCI study product was administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to receive up to 4 cycles of chemotherapy at 3-week intervals: 1 standard dose of CDDP and of vinorelbine intravenously on the first day of each cycle (starting at Week -1) and 1 standard dose of vinorelbine intravenously on Day 8 of each cycle, concomitantly with MAGE-A3 ASCI administration.

Arm type	Experimental
Investigational medicinal product name	recMAGE-A3 recombinant protein formulated in AS15 adjuvant
Investigational medicinal product code	recMAGE-A3 + AS15
Other name	GSK1572932A; MAGE-A3 ASCI
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Patients received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was to be administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area.

Arm title	Chemotherapy/MAGE-A3 ASCI Group

Arm description:

This group (Cohort 2 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors who are due for chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product after receiving cis-diaminedichloroplatine (CDDP) + vinorelbine [either Vinorelbine or Pierre Fabre's Navelbine chemotherapy. The 8-dose course of MAGE-A3 ASCI was administered according to a 3-week intervals schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to received at least 2 cycles of chemotherapy ,(1 standard dose of CDDP and of vinorelbine intravenously on the first day of each cycle and 1 dose of vinorelbine on Day 8 of each cycle), the last dose received to 4 weeks prior Dose 1 of MAGE-A3 ASCI. No additional chemotherapy was administered to patients from Week 0 onwards.

Arm type	Experimental

Investigational medicinal product name	recMAGE-A3 recombinant protein formulated in AS15 adjuvant
Investigational medicinal product code	recMAGE-A3 + AS15
Other name	GSK1572932A; MAGE-A3 ASCI
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Patients received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was to be administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area.

Arm title	MAGE-A3 ASCI Group

Arm description:

This group (Cohort 3 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors who are not due for cis-diaminedichloroplatine (CDDP) + vinorelbine chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to have had their tumor resected at least 4 to 8 weeks prior to receiving Dose 1 of MAGE-A3 ASCI product and to receive no chemo-/radiotherapy during the entire duration of the study.

Arm type	Experimental
Investigational medicinal product name	recMAGE-A3 recombinant protein formulated in AS15 adjuvant
Investigational medicinal product code	recMAGE-A3 + AS15
Other name	GSK1572932A; MAGE-A3 ASCI
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Patients received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was to be administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area.

Arm title	Chemo/radiotherapy-MAGE-A3 ASCI Group

Arm description:

This group (Cohort 4 as per protocol summary) consisted in patients aged 18 years or more with unresectable stage III tumors following chemotherapy and radiotherapy who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was to be administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to have received their last dose of chemotherapy (cis-diaminedichloroplatine [CDDP] + vinorelbine [either the generic Vinorelbine or Pierre Fabre’s Navelbine]) and/or radiotherapy 2 to 6 weeks prior to receiving Dose 1 of MAGE-A3 ASCI product. No additional chemo-/radiotherapy was administered to patients in this cohort from Week 0 onwards.

Arm type	Experimental
Investigational medicinal product name	recMAGE-A3 recombinant protein formulated in AS15 adjuvant
Investigational medicinal product code	recMAGE-A3 + AS15
Other name	GSK1572932A; MAGE-A3 ASCI
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Patients received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was to be administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area.

Number of subjects in period 1[1]	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/MAGE-A3 ASCI Group	MAGE-A3 ASCI Group
Started	19	18	18
Completed	15	14	8
Not completed	4	4	10
Adverse event, serious fatal	-	-	-
Adverse event, non-fatal	1	-	2
Recurrence/Disease Progression	-	4	6
Second cancer, reduced compliance and comorbidity	3	-	-
Other reasons	-	-	2

Number of subjects in period 1[1]	Chemo/radiotherapy -MAGE-A3 ASCI Group
Started	12
Completed	8
Not completed	4
Adverse event, serious fatal	1
Adverse event, non-fatal	-
Recurrence/Disease Progression	3
Second cancer, reduced compliance and comorbidity	-
Other reasons	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 70 patients were screened towards participation in the study. Out of these 70 patients, 67 were assessed as eligible for treatment and were administered the study MAGE-A3 ASCI study treatment.

Baseline characteristics

Reporting groups

Reporting group title	Chemotherapy + MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 1 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors, who are due for chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product concurrently with cis-diaminedichloroplatine (CDDP) + vinorelbine [either Vinorelbine or Pierre Fabre's Navelbine] chemotherapy. The 8-dose course of MAGE-A3 ASCI study product was administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to receive up to 4 cycles of chemotherapy at 3-week intervals: 1 standard dose of CDDP and of vinorelbine intravenously on the first day of each cycle (starting at Week -1) and 1 standard dose of vinorelbine intravenously on Day 8 of each cycle, concomitantly with MAGE-A3 ASCI administration.

Reporting group title	Chemotherapy/MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 2 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors who are due for chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product after receiving cis-diaminedichloroplatine (CDDP) + vinorelbine [either Vinorelbine or Pierre Fabre's Navelbine chemotherapy. The 8-dose course of MAGE-A3 ASCI was administered according to a 3-week intervals schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to received at least 2 cycles of chemotherapy ,(1 standard dose of CDDP and of vinorelbine intravenously on the first day of each cycle and 1 dose of vinorelbine on Day 8 of each cycle), the last dose received to 4 weeks prior Dose 1 of MAGE-A3 ASCI. No additional chemotherapy was administered to patients from Week 0 onwards.

Reporting group title	MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 3 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors who are not due for cis-diaminedichloroplatine (CDDP) + vinorelbine chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to have had their tumor resected at least 4 to 8 weeks prior to receiving Dose 1 of MAGE-A3 ASCI product and to receive no chemo-/radiotherapy during the entire duration of the study.

Reporting group title	Chemo/radiotherapy-MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 4 as per protocol summary) consisted in patients aged 18 years or more with unresectable stage III tumors following chemotherapy and radiotherapy who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was to be administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to have received their last dose of chemotherapy (cis-diaminedichloroplatine [CDDP] + vinorelbine [either the generic Vinorelbine or Pierre Fabre's Navelbine]) and/or radiotherapy 2 to 6 weeks prior to receiving Dose 1 of MAGE-A3 ASCI product. No additional chemo-/radiotherapy was administered to patients in this cohort from Week 0 onwards.

Reporting group values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/MAGE-A3 ASCI Group	MAGE-A3 ASCI Group
Number of subjects	19	18	18
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			

Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	58.7	60.6	67.1
standard deviation	± 10.3	± 6.37	± 9.81
Gender categorical Units: Subjects			
Female	14	15	16
Male	5	3	2

Reporting group values	Chemo/radiotherapy -MAGE-A3 ASCI Group	Total	
Number of subjects	12	67	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	59.9		
standard deviation	± 7.33	-	
Gender categorical Units: Subjects			
Female	7	52	
Male	5	15	

End points

End points reporting groups

Reporting group title	Chemotherapy + MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 1 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors, who are due for chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product concurrently with cis-diaminedichloroplatine (CDDP) + vinorelbine [either Vinorelbine or Pierre Fabre's Navelbine] chemotherapy. The 8-dose course of MAGE-A3 ASCI study product was administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to receive up to 4 cycles of chemotherapy at 3-week intervals: 1 standard dose of CDDP and of vinorelbine intravenously on the first day of each cycle (starting at Week -1) and 1 standard dose of vinorelbine intravenously on Day 8 of each cycle, concomitantly with MAGE-A3 ASCI administration.

Reporting group title	Chemotherapy/MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 2 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors who are due for chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product after receiving cis-diaminedichloroplatine (CDDP) + vinorelbine [either Vinorelbine or Pierre Fabre's Navelbine chemotherapy. The 8-dose course of MAGE-A3 ASCI was administered according to a 3-week intervals schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to received at least 2 cycles of chemotherapy ,(1 standard dose of CDDP and of vinorelbine intravenously on the first day of each cycle and 1 dose of vinorelbine on Day 8 of each cycle), the last dose received to 4 weeks prior Dose 1 of MAGE-A3 ASCI. No additional chemotherapy was administered to patients from Week 0 onwards.

Reporting group title	MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 3 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors who are not due for cis-diaminedichloroplatine (CDDP) + vinorelbine chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to have had their tumor resected at least 4 to 8 weeks prior to receiving Dose 1 of MAGE-A3 ASCI product and to receive no chemo-/radiotherapy during the entire duration of the study.

Reporting group title	Chemo/radiotherapy-MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 4 as per protocol summary) consisted in patients aged 18 years or more with unresectable stage III tumors following chemotherapy and radiotherapy who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was to be administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to have received their last dose of chemotherapy (cis-diaminedichloroplatine [CDDP] + vinorelbine [either the generic Vinorelbine or Pierre Fabre's Navelbine]) and/or radiotherapy 2 to 6 weeks prior to receiving Dose 1 of MAGE-A3 ASCI product. No additional chemo-/radiotherapy was administered to patients in this cohort from Week 0 onwards.

Primary: Number of subjects seropositive for anti-Melanoma AntiGEn (MAGE)-A3 antibodies

End point title	Number of subjects seropositive for anti-Melanoma AntiGEn (MAGE)-A3 antibodies[1]

End point description:

A seropositive subject for anti-MAGE-A3 antibodies was a subject with anti-MAGE-A3 antibodies ≥ the seropositivity cut-off of 27 Enzyme-linked immunosorbent assay (ELISA) units per millilitre (EL.U/mL). The W6 time point was only applicable to Chemotherapy + MAGE-A3 Group. The Study End (SE) time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3

ASCI groups and the Study Early Termination (ET) time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

At Screening (SCR), At Weeks 6, 7, 13, 16, 19, 22 and 27 (W6, W7, W13, W16, W19, W22 and W27) and at Study End (SE) or Study Early Termination (ET)

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	16	12
Units: Subjects				
Anti-MAGE-A3, SCR (N=19;18;16;12)	1	4	0	1
Anti-MAGE-A3, W6 (N= 13;0;0;0)	12	0	0	0
Anti-MAGE-A3, W7 (N=11;15;13;10)	11	14	13	9
Anti-MAGE-A3, W13 (N=12;15;12;9)	12	15	12	9
Anti-MAGE-A3, W16 (N=12;16;10;8)	12	16	10	8
Anti-MAGE-A3, W19 (N=13;14;11;8)	13	14	11	8
Anti-MAGE-A3, W22 (N=15;12;8;8)	15	12	8	8
Anti-MAGE-A3, W27 (N=15;13;9;7)	15	13	9	7
Anti-MAGE-A3, SE (N=2;4;4;0)	1	4	4	0
Anti-MAGE-A3, ET (N=0;0;0;2)	0	0	0	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of humoral responders as regards anti-Melanoma AntiGEn (MAGE)-A3 antibodies

End point title	Number of humoral responders as regards anti-Melanoma AntiGEn (MAGE)-A3 antibodies[2]

End point description:

A seropositive/seronegative subject for anti-MAGE-A3 antibodies was a subject with anti-MAGE-A3 antibodies ≥/< the seropositivity cut-off of 27 Enzyme-linked immunosorbent assay (ELISA) units per millilitre (EL.U/mL). A humoral responder as regards anti-MAGE-A3 antibodies was defined as 1) for initially seronegative patients, a patient with post-administration Anti-MAGE-A3 antibody concentration ≥ 27 EL.U/mL; 2) for initially seropositive patients: post-administration antibody concentration ≥ 2 fold the pre-vaccination antibody concentration.. The Week 6 time point was only applicable to Chemotherapy + MAGE-A3 Group. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

At Weeks 6, 7, 13, 16, 19, 22 and 27 (W6, W7, W13, W16, W19, W22 and W27) and at Study End (SE) or Study Early termination (ET)

Notes:

[2] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	16	12	10
Units: Subjects				
Anti-MAGE-A3, W6 (N=13;0;0;0)	12	0	0	0
Anti-MAGE-A3, W7 (N=11;15;12;10)	11	14	12	9
Anti-MAGE-A3, W13 (N=12;15;10;9)	12	15	10	9
Anti-MAGE-A3, W16 (N=12;16;8;8)	12	16	8	8
Anti-MAGE-A3, W19 (N=13;14;9;8)	13	14	9	8
Anti-MAGE-A3, W22 (N=15;12;8;8)	15	12	8	8
Anti-MAGE-A3, W27 (N=15;13;8;7)	15	13	8	7
Anti-MAGE-A3, SE (N=2;4;3;0)	1	4	3	0
Anti-MAGE-A3, ET (N=0;0;0;2)	0	0	0	2

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations for anti-Melanoma AntiGEn (MAGE)-A3 antibodies

End point title	Concentrations for anti-Melanoma AntiGEn (MAGE)-A3 antibodies[3]

End point description:

The seropositivity cut-off of the assay was ≥ 27 Enzyme-linked immunosorbent assay (ELISA) units per millilitre (EL.U/mL). The Week 6 time point was only applicable to Chemotherapy + MAGE-A3 Group. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

At Screening (SCR), At Weeks 6, 7, 13, 16, 19, 22 and 27 (W6, W7, W13, W16, W19, W22 and W27) and at Study End (SE) or Study Early termination (ET)

Notes:

[3] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	16	12
Units: EL.U/mL				
geometric mean (confidence interval 95%)				

Anti-MAGE-A3, SCR (N=19;18;16;12)	11 (9.5 to 12.8)	13.9 (10 to 19.2)	10.6 (9.3 to 12.1)	11.8 (9.2 to 15.1)
Anti-MAGE-A3, W6 (N= 13;0;0;0)	330.5 (93.8 to 1164.1)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Anti-MAGE-A3, W7 (N=11;15;13;10)	438.8 (138.2 to 1393.9)	1171.1 (413.5 to 3316.6)	698 (370.2 to 1316)	975.3 (151.3 to 6288.8)
Anti-MAGE-A3, W13 (N=12;15;12;9)	1711.7 (804 to 3644.6)	4336.1 (2971.4 to 6327.6)	3051.3 (1808.9 to 5147.2)	4927.5 (1147.8 to 21152.5)
Anti-MAGE-A3, W16 (N=12;16;10;8)	4250.4 (2244.4 to 8049.4)	5433.6 (3704.4 to 7969.8)	4360.1 (2484 to 7653.2)	5219 (1189.5 to 22898)
Anti-MAGE-A3, W19 (N=13;14;11;8)	4828.8 (2955.6 to 7889.1)	5217.6 (3888.8 to 7000.4)	4298.1 (2802.1 to 6592.7)	5557.9 (1138 to 27143.6)
Anti-MAGE-A3, W22 (N=15;12;8;8)	4097.8 (2645.3 to 6347.8)	4442.7 (3041.7 to 6489.1)	4447.5 (2381.3 to 8306.4)	8301.9 (5111 to 13484.9)
Anti-MAGE-A3, W27 (N=15;13;9;7)	3591.2 (2199.9 to 5862.4)	4339.9 (3305.4 to 5698.1)	4213.4 (2386.1 to 7440.3)	6406.5 (3594.9 to 11417.1)
Anti-MAGE-A3, SE (N=2;4;4;0)	16.7 (0 to 11599)	3155.1 (1306 to 7622.2)	2974.1 (429.5 to 20592.2)	0 (0 to 0)
Anti-MAGE-A3, ET (N=0;0;0;2)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	865.2 (227.9 to 3284.3)

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects seropositive for anti-protein D (PD) antibodies

End point title	Number of subjects seropositive for anti-protein D (PD) antibodies[4]

End point description:

A seropositive subject for anti-PD antibodies was a subject with anti-PD antibodies ≥ the seropositivity cut-off of 100 Enzyme-linked immunosorbent assay (ELISA) units per millilitre (EL.U/mL). The Week 6 time point was only applicable to Chemotherapy + MAGE-A3 Group. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

At Screening (SCR), At Weeks 6, 7, 13, 16, 19, 22 and 27 (W6, W7, W13, W16, W19, W22 and W27) and at Study End (SE) or Study Early termination (ET)

Notes:

[4] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	17	17	12
Units: Subjects				
Anti-PD, SCR (N=19;17;17;12)	3	4	6	1
Anti-PD, W6 (N=14;0;0;0)	14	0	0	0

Anti-PD, W7 (N=12;17;14;11)	12	16	14	11
Anti-PD, W13 (N=15;15;12;9)	15	15	12	9
Anti-PD, W16 (N=15;16;11;8)	15	16	11	8
Anti-PD, W19 (N=15;14;11;8)	15	14	11	8
Anti-PD, W22 (N=15;12;9;8)	15	12	9	8
Anti-PD, W27 (N=15;13;9;7)	15	13	9	7
Anti-PD, SE (N=2;4;4;0)	1	4	4	0
Anti-PD, ET (N=0;0;0;2)	0	0	0	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of humoral responders as regards anti-protein D (PD) antibodies

End point title	Number of humoral responders as regards anti-protein D (PD) antibodies[5]

End point description:

A seropositive/seronegative subject for anti-PD antibodies was a subject with anti-PD antibodies ≥/< the seropositivity cut-off of 100 Enzyme-linked immunosorbent assay (ELISA) units per millilitre (EL.U/mL). A humoral responder as regards anti-PD antibodies was defined as 1) for initially seronegative patients, a patient with post-administration anti-PD antibody concentration ≥ 100 EL.U/mL; 2) for initially seropositive patients: post-administration antibody concentration ≥ 2 fold the pre-vaccination antibody concentration. The Week 6 time point was only applicable to Chemotherapy + MAGE-A3 Group. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

At Weeks 6, 7, 13, 16, 19, 22 and 27 (W6, W7, W13, W16, W19, W22 and W27) and at Study End (SE) or Study Early termination (ET)

Notes:

[5] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	16	13	11
Units: Subjects				
Anti-PD, W6 (N=14;0;0;0)	14	0	0	0
Anti-PD, W7 (N=12;16;13;11)	12	15	13	11
Anti-PD, W13 (N=15;14;11;9)	15	14	11	9
Anti-PD, W16 (N=15;15;10;8)	15	15	10	8
Anti-PD, W19 (N=15;13;10;7)	15	13	10	7
Anti-PD, W22 (N=15;11;9;8)	15	11	9	8
Anti-PD, W27 (N=15;12;9;7)	15	12	9	7
Anti-PD, SE (N=2;4;3;0)	1	4	3	0
Anti-PD, ET (N=0;0;0;2)	0	0	0	2

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations for anti-protein D (PD) antibodies

End point title	Concentrations for anti-protein D (PD) antibodies[6]

End point description:

The seropositivity cut-off of the assay was ≥ 100 Enzyme-linked immunosorbent assay (ELISA) units per millilitre (EL.U/mL). The Week 6 time point was only applicable to Chemotherapy + MAGE-A3 Group. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

At Screening (SCR), At Weeks 6, 7, 13, 16, 19, 22 and 27 (W6, W7, W13, W16, W19, W22 and W27) and at Study End (SE) or Study Early termination (ET)

Notes:

[6] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	17	17	12
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PD, SCR (N=19;17;17;12)	65.9 (47.7 to 91.1)	68.2 (49.5 to 94.1)	95.5 (51.2 to 177.9)	53.4 (46.2 to 61.7)
Anti-PD, W6 (N=14;0;0;0)	5126.7 (2628.8 to 9998)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Anti-PD, W7 (N=12;17;14;11)	5876.6 (2883.1 to 11978.4)	5871.1 (2309.1 to 14928.1)	6602.4 (2562.9 to 17008.8)	5393 (1649.1 to 17635.9)
Anti-PD, W13 (N=15;15;12;9)	12842.6 (8672.1 to 19018.6)	16939.9 (9795.5 to 29295.4)	16165.9 (7282.9 to 35883.6)	13156.1 (6284.7 to 27540.5)
Anti-PD, W16 (N=15;16;11;8)	17930.8 (12187.9 to 26379.8)	18029.7 (10977.9 to 29611.4)	22195.2 (9535.6 to 51662.1)	13226.5 (8515.5 to 20543.7)
Anti-PD, W19 (N=15;14;11;8)	19471.8 (12865.4 to 29470.6)	17596.2 (11081.5 to 27940.7)	23456 (11664.4 to 47168)	15897.8 (9817.5 to 25743.7)
Anti-PD, W22 (N=15;12;9;8)	19050.7 (12332.1 to 29429.6)	18349.4 (10737.7 to 31356.7)	27568.7 (10652.2 to 71349.7)	16729.1 (10358 to 27018.9)
Anti-PD, W27 (N=15;13;9;7)	16698.6 (10475 to 26619.7)	14190.5 (9343.3 to 21552.4)	27919.6 (13083.6 to 59578.7)	13906.9 (8197.6 to 23592.3)

Anti-PD, SE (N=2;4;4;0)	231.8 (0 to 67660000)	10620.8 (7991.3 to 14115.6)	11438.9 (2879.3 to 45444.1)	0 (0 to 0)
Anti-PD, ET (N=0;0;0;2)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	8836.1 (0 to 28094000)

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients seropositive as regards MAGE-A3 Cluster of Differentiation (CD)4 T-cell immunogenicity

End point title	Number of patients seropositive as regards MAGE-A3 Cluster of Differentiation (CD)4 T-cell immunogenicity[7]

End point description:

A patient seropositive as regards MAGE-A3 CD4 T-cell immunogenicity was defined as a patient with geometric mean ratios (GMRs) between stimulated and unstimulated PBMC in a multiwell assay for the percentage of interferon (IFN)- and tumor necrosis factor (TNF)- double positive CD4 T-cells responding to MAGE-A3 overlapping peptide stimulation (IFN-g+TNF-aDble+ CD4) ≥ the 8.4% seropositivity cut-off. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

At screening (SCR), at Weeks 13 and 27 (W13 and W27), and at Study End (SE) or Study Early termination (ET)

Notes:

[7] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	17	11	8
Units: Subjects				
IFN-g+TNF-aDble+ CD4, SCR (N=13;17;11;8)	3	1	0	1
IFN-g+TNF-aDble+ CD4, W13 (N=12;13;8;8)	7	4	2	5
IFN-g+TNF-aDble+ CD4, W27 (N=14;13;6;7)	9	4	4	6
IFN-g+TNF-aDble+ CD4, SE (N=2;1;1;0)	0	0	0	0
IFN-g+TNF-aDble+ CD4, ET (N=0;0;0;2)	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients responders as MAGE-A3 Cluster of Differentiation (CD)4 T-cell immunogenicity

End point title	Number of patients responders as MAGE-A3 Cluster of Differentiation (CD)4 T-cell immunogenicity[8]

End point description:

A patient seropositive/seronegative for MAGE-A3 Cluster of Differentiation (CD)4 T-cell was a patient with geometric mean ratios (GMRs) for the percentage of IFN- and TNF- double positive CD4 T-cells responding to MAGE-A3 peptide stimulation (IFN-g+TNF-aDble+ CD4) ≥ /< the 8.4% cut-off. A patient responder as MAGE-A3 CD4 T-cell was defined as follows: 1/for initially seronegative patients: post-administration antibody titer ≥ 8.4% for IFN-g+TNF-aDble+ CD4, or 2/for initially seropositive patients: post-administration antibody titer ≥ 4 fold the pre-vaccination antibody titer. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group. Please note that overlap was reported for W13 and W17, for 3 and 2 patients in the Chemotherapy + MAGE-A3 ASCI and Chemotherapy/MAGE-A3 ASCI groups, respectively, for whom a cellular response was found.

End point type	Primary

End point timeframe:

At Weeks 13 and 27 (W13 and W27), and at Study End (SE) or Study Early termination (ET)

Notes:

[8] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	13	6	4
Units: Subjects				
IFN-g+TNF-aDble+ CD4, W13 (N=7;12;6;4)	4	3	0	2
IFN-g+TNF-aDble+ CD4, W27 (N=9;13;4;4)	3	3	2	4
IFN-g+TNF-aDble+ CD4, SE (N=2;1;1;0)	0	0	0	0
IFN-g+TNF-aDble+ CD4, ET (N=0;0;0;2)	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients seropositive as regards MAGE-A3 Cluster of Differentiation (CD)8 T-cell immunogenicity

End point title	Number of patients seropositive as regards MAGE-A3 Cluster of Differentiation (CD)8 T-cell immunogenicity[9]

End point description:

A patient seropositive as regards MAGE-A3 CD8 T-cell immunogenicity was defined as a patient with geometric mean ratios (GMRs) between stimulated and unstimulated PBMC in a multiwell assay for the percentage of IFN- and TNF- double positive CD8 T-cells responding to MAGE-A3 overlapping peptide stimulation (IFN-g+TNF-aDble+ CD8) ≥ the 3.2% seropositivity cut-off. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

At screening (SCR), at Weeks 13 and 27 (W13 and W27), and at Study End (SE) or Study Early termination (ET)

Notes:

[9] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	17	11	8
Units: Subjects				
IFN-g+TNF-aDble+ CD8, SCR (N=13;17;11;8)	0	2	0	0
IFN-g+TNF-aDble+ CD8, W13 (N=12;13;8;8)	2	1	2	1
IFN-g+TNF-aDble+ CD8, W27 (N=14;13;6;7)	1	3	0	1
IFN-g+TNF-aDble+ CD8, SE (N=2;1;1;0)	1	0	0	0
IFN-g+TNF-aDble+ CD8, ET (N=0;0;0;2)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients responders as MAGE-A3 Cluster of Differentiation (CD)8 T-cell immunogenicity

End point title	Number of patients responders as MAGE-A3 Cluster of Differentiation (CD)8 T-cell immunogenicity[10]

End point description:

A patient seropositive/seronegative for MAGE-A3 Cluster of Differentiation (CD)8 T-cell was a patient with geometric mean ratios (GMRs) for the percentage of IFN- and TNF- double positive CD8 T-cells responding to MAGE-A3 peptide stimulation (IFN-g+TNF-aDble+ CD8) ≥ /< the 3.2% cut-off. A patient responder as MAGE-A3 CD8 T-cell was defined as follows: 1/for initially seronegative patients: post-administration antibody titer ≥ 3.2% for IFN-g+TNF-aDble+ CD8, or 2/for initially seropositive patients: post-administration antibody titer ≥ 4 fold the pre-vaccination antibody titer. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

At Weeks 13 and 27 (W13 and W27), and at Study End (SE) or Study Early termination (ET)

Notes:

[10] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	13	6	4
Units: Subjects				
IFN-g+TNF-aDble+ CD8, W13 (N=7;12;6;4)	1	0	0	1
IFN-g+TNF-aDble+ CD8, W27 (N=9;13;4;4)	0	1	0	1
IFN-g+TNF-aDble+ CD8, SE (N=2;1;1;0)	0	0	0	0
IFN-g+TNF-aDble+ CD8, ET (N=0;0;0;2)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients with abnormal haemoglobin laboratory values by maximum grade

End point title	Number of patients with abnormal haemoglobin laboratory values by maximum grade[11]

End point description:

The status of each patient as regards haemoglobin (HAE) laboratory values at baseline and from screening up to Study End (SE) (Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups) or Study Early termination (ET) (Chemo/radiotherapy-MAGE-A3 ASCI Group) was collected and graded according to the Common Terminology Criteria (CTC) Adverse event terminology, version 3.0. By screening status, it was assessed whether the post-treatment values were above, below or in the normal range. Screening CTC grade statuses were Grade 0 (G0) and G1. Overall study post-treatment (PT) CTC grade statuses were, G0, G1, G2, G3, G4, G5 and Unknown (UNK).

End point type	Primary

End point timeframe:

At screening (SCR) and throughout the entire study duration, from SCR to Study End (SE) or Study Early termination (ET)

Notes:

[11] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	18	12
Units: Subjects				
HAE - SCR G0; PT G1	7	1	1	0
HAE - SCR G0; PT G2	0	0	0	0
HAE - SCR G0; PT G3	0	0	0	0
HAE - SCR G0; PT G4	0	0	0	0
HAE - SCR G0; PT G5	0	0	0	0
HAE - SCR G0; PT UNK	0	0	4	2
HAE - SCR G1; PT G1	5	8	5	2
HAE - SCR G1; PT G2	2	0	0	0

HAE - SCR G1; PT G3	0	0	0	0
HAE - SCR G1; PT G4	0	0	0	0
HAE - SCR G1; PT G5	0	0	0	0
HAE - SCR G1; PT UNK	1	1	1	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients with abnormal leukocytes laboratory values by maximum grade

End point title	Number of patients with abnormal leukocytes laboratory values by maximum grade[12]

End point description:

The status of each patient as regards leukocytes (LEU) laboratory values at baseline and from screening up to Study End (SE) (Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups) or Study Early termination (ET) (Chemo/radiotherapy-MAGE-A3 ASCI Group) was collected and graded according to the Common Terminology Criteria (CTC) Adverse event terminology, version 3.0. By screening status, it was assessed whether the post-treatment values were above, below or in the normal range. Screening CTC grade statuses were Grade 0 (G0) and G1. Overall study post-treatment (PT) CTC grade statuses were, G0, G1, G2, G3, G4, G5 and Unknown (UNK).

End point type	Primary

End point timeframe:

At screening (SCR) and throughout the entire study duration, from SCR to Study End (SE) or Study Early termination (ET)

Notes:

[12] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	18	12
Units: Subjects				
LEU - SCR G0; PT G1	0	0	1	0
LEU - SCR G0; PT G2	0	0	0	0
LEU - SCR G0; PT G3	0	0	0	0
LEU - SCR G0; PT G4	0	0	0	0
LEU - SCR G0; PT G5	0	0	0	0
LEU - SCR G0; PT UNK	1	1	5	4
LEU - SCR G1; PT G1	0	0	0	2
LEU - SCR G1; PT G2	0	0	0	0
LEU - SCR G1; PT G3	0	0	0	0
LEU - SCR G1; PT G4	0	0	0	0
LEU - SCR G1; PT G5	0	0	0	0
LEU - SCR G1; PT UNK	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients with abnormal lymphopenia laboratory values by maximum grade

End point title	Number of patients with abnormal lymphopenia laboratory values by maximum grade[13]

End point description:

The status of each patient as regards lymphopenia (LYM) laboratory values at baseline and from screening up to Study End (SE) (Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups) or Study Early termination (ET) (Chemo/radiotherapy-MAGE-A3 ASCI Group) was collected and graded according to the Common Terminology Criteria (CTC) Adverse event terminology, version 3.0. By screening status, it was assessed whether the post-treatment values were above, below or in the normal range. Screening CTC grade statuses were Unknown (UNK), Grade 0 (G0), G1, G2, G3. Overall study post-treatment (PT) CTC grade statuses were, G0, G1, G2, G3, G4, G5 and Unknown (UNK).

End point type	Primary

End point timeframe:

At screening (SCR) and throughout the entire study duration, from SCR to Study End (SE) or Study Early termination (ET)

Notes:

[13] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	18	12
Units: Subjects				
LYM - SCR UNK; PT G1	0	0	0	1
LYM - SCR UNK; PT G2	0	0	0	0
LYM - SCR UNK; PT G3	0	0	0	0
LYM - SCR UNK; PT G4	0	0	0	0
LYM - SCR UNK; PT G5	0	0	0	0
LYM - SCR UNK; PT UNK	0	0	0	0
LYM - SCR G0; PT G1	1	0	2	1
LYM - SCR G0; PT G2	0	0	0	0
LYM - SCR G0; PT G3	0	0	0	0
LYM - SCR G0; PT G4	0	0	0	0
LYM - SCR G0; PT G5	0	0	0	0
LYM - SCR G0; PT UNK	1	1	4	0
LYM - SCR G1; PT G1	0	1	0	0
LYM - SCR G1; PT G2	0	0	0	0
LYM - SCR G1; PT G3	0	0	0	0
LYM - SCR G1; PT G4	0	0	0	0
LYM - SCR G1; PT G5	0	0	0	0
LYM - SCR G1; PT UNK	0	0	1	1
LYM - SCR G2; PT G1	0	0	0	1
LYM - SCR G2; PT G2	0	1	1	1
LYM - SCR G2; PT G3	0	0	0	0
LYM - SCR G2; PT G4	0	0	0	0
LYM - SCR G2; PT G5	0	0	0	0

LYM - SCR G2; PT UNK	0	0	0	3
LYM - SCR G3; PT G1	0	0	0	1
LYM - SCR G3; PT G2	0	0	0	2
LYM - SCR G3; PT G3	0	0	1	0
LYM - SCR G3; PT G4	0	0	0	0
LYM - SCR G3; PT G5	0	0	0	0
LYM - SCR G3; PT UNK	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients with abnormal neutrophils laboratory values by maximum grade

End point title	Number of patients with abnormal neutrophils laboratory values by maximum grade[14]

End point description:

The status of each patient as regards neutrophils (NEU) laboratory values at baseline and from screening up to Study End (SE) (Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups) or Study Early termination (ET) (Chemo/radiotherapy-MAGE-A3 ASCI Group) was collected and graded according to the Common Terminology Criteria (CTC) Adverse event terminology, version 3.0. By screening status, it was assessed whether the post-treatment values were above, below or in the normal range. Screening CTC grade statuses were Grade 0 (G0) and G1. Overall study post-treatment (PT) CTC grade statuses were, G0, G1, G2, G3, G4, G5 and Unknown (UNK).

End point type	Primary

End point timeframe:

At screening (SCR) and throughout the entire study duration, from SCR to Study End (SE) or Study Early termination (ET)

Notes:

[14] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	18	12
Units: Subjects				
NEU - SCR G0; PT G1	0	0	1	1
NEU - SCR G0; PT G2	0	0	0	0
NEU - SCR G0; PT G3	0	0	0	0
NEU - SCR G0; PT G4	0	0	0	0
NEU - SCR G0; PT G5	0	0	0	0
NEU - SCR G0; PT UNK	1	0	5	4
NEU - SCR G1; PT G1	0	0	0	0
NEU - SCR G1; PT G2	0	0	0	0
NEU - SCR G1; PT G3	0	0	0	0
NEU - SCR G1; PT G4	0	0	0	0
NEU - SCR G1; PT G5	0	0	0	0
NEU - SCR G1; PT UNK	0	1	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients with abnormal platelets laboratory values by maximum grade

End point title	Number of patients with abnormal platelets laboratory values by maximum grade[15]

End point description:

The status of each patient as regards platelets (PLA) laboratory values at baseline and from screening up to Study End (SE) (Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups) or Study Early termination (ET) (Chemo/radiotherapy-MAGE-A3 ASCI Group) was collected and graded according to the Common Terminology Criteria (CTC) Adverse event terminology, version 3.0. By screening status, it was assessed whether the post-treatment values were above, below or in the normal range. Screening CTC grade statuses were Grade 0 (G0) and G1. Overall study post-treatment (PT) CTC grade statuses were, G0, G1, G2, G3, G4, G5 and Unknown (UNK).

End point type	Primary

End point timeframe:

At screening (SCR) and throughout the entire study duration, from SCR to Study End (SE) or Study Early termination (ET)

Notes:

[15] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	18	12
Units: Subjects				
PLA - SCR G0; PT G1	0	0	0	0
PLA - SCR G0; PT G2	0	0	0	0
PLA - SCR G0; PT G3	0	0	0	0
PLA - SCR G0; PT G4	0	0	0	0
PLA - SCR G0; PT G5	0	0	0	0
PLA - SCR G0; PT UNK	1	1	5	3
PLA - SCR G1; PT G1	0	0	1	1
PLA - SCR G1; PT G2	0	0	0	0
PLA - SCR G1; PT G3	0	0	0	0
PLA - SCR G1; PT G4	0	0	0	0
PLA - SCR G1; PT G5	0	0	0	0
PLA - SCR G1; PT UNK	0	1	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients with adverse events (AEs) by maximum grade

End point title	Number of patients with adverse events (AEs) by maximum grade[16]

End point description:

An AE was defined any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product) reported in addition to those solicited during the clinical study. Patients' statuses as regards AEs reported from screening up to SE/ET was collected and graded according to the Common Terminology Criteria (CTC) AE terminology, version 3.0. The maximum grades reported were compiled. Grades compiled were Grade (G) 0, G1, G2, G3 and G4 for all groups as well as G5 for the Chemo/radiotherapy-MAGE-A3 ASCI Group only. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

Throughout the entire study duration, from screening (SCR) to Study End (SE) or Study Early termination (ET)

Notes:

[16] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	18	12
Units: Subjects				
G1 AEs maximum	0	8	1	5
G2 AEs maximum	3	8	11	5
G3 AEs maximum	5	2	3	1
G4 AEs maximum	11	0	2	0
G5 AEs maximum	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients with potential immune-mediated diseases (pIMDs)

End point title	Number of patients with potential immune-mediated diseases (pIMDs)[17]

End point description:

pIMDs are a subset of AEs that include both clearly autoimmune diseases and also other inflammatory and/or neurologic disorders which may or may not have an autoimmune etiology. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET time point is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

Throughout the entire study duration, from screening (SCR) to Study End (SE) or Study Early termination (ET)

Notes:

[17] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	18	12
Units: Subjects				
pIMD(s)	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients with unsolicited adverse events (AEs), irrespective of grade

End point title	Number of patients with unsolicited adverse events (AEs), irrespective of grade[18]

End point description:

An AE was any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product

End point type	Primary

End point timeframe:

Within the 31-day follow-up period post study product administration.

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	18	12
Units: Subjects				
Any AE	19	18	17	11

Statistical analyses

No statistical analyses for this end point

Primary: Number of patients with serious adverse events (SAEs)

End point title	Number of patients with serious adverse events (SAEs)[19]

End point description:

A SAE is any untoward medical occurrence that resulted in death, was life-threatening,

required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect in the offspring of a study subject, or was a Grade 4 AE according to the Common Terminology Criteria for Adverse Events, Version 3.0. Progression of disease or cancer recurrence were not reported as a SAE. However, if the progression of the underlying disease was greater than that which would normally be expected for the patient. If a causal relationship between treatment or protocol design/procedures and the disease progression/recurrence was assessed, the event was reported as SAE. Any new cancer (not related to the cancer under study) was reported as a SAE. The SE time point is only applicable to the Chemotherapy + MAGE-A3, Chemotherapy/MAGE-A3 ASCI and MAGE-A3 ASCI groups and the ET is only applicable to the Chemo/radiotherapy-MAGE-A3 ASCI Group.

End point type	Primary

End point timeframe:

Throughout the entire study duration, from screening (SCR) to Study End (SE) or Study Early termination (ET)

Notes:

[19] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Chemotherapy + MAGE-A3 ASCI Group	Chemotherapy/ MAGE-A3 ASCI Group	MAGE-A3 ASCI Group	Chemo/radiotherapy-MAGE-A3 ASCI Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	18	12
Units: Subjects				
Any SAE	12	0	4	3

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

SAEs: From screening to study end/early termination; Unsolicited AEs: Within the 31-day follow-up period post study product administration.

Adverse event reporting additional description:

The occurrence of reported AEs (all/related) was not available and is encoded as equal to the number of subjects affected.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Chemotherapy + MAGE-A3 Group

Reporting group description:

This group (Cohort 1 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors, who are due for chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product concurrently with cis-diaminedichloroplatine (CDDP) + vinorelbine [either Vinorelbine®or Pierre Fabre's Navelbine®] chemotherapy. The 8-dose course of MAGE-A3 ASCI study product was administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to receive up to 4 cycles of chemotherapy at 3-week intervals: 1 standard dose of CDDP and of vinorelbine intravenously on the first day of each cycle (starting at Week -1) and 1 standard dose of vinorelbine intravenously on Day 8 of each cycle, concomitantly with MAGE-A3 ASCI administration.

Reporting group title	Chemotherapy/MAGE-A3 ASCI Group

Reporting group description:

This g roup (Cohort 2 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors who are due for chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product after receiving cis-diaminedichloroplatine (CDDP) + vinorelbine [either Vinorelbine®or Pierre Fabre's Navelbine®] chemotherapy. The 8-dose course of MAGE-A3 ASCI was administered according to a 3-week intervals schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to receive at least 2 cycles of chemotherapy ,(1 standard dose of CDDP and of vinorelbine intravenously on the first day of each cycle and 1 dose of vinorelbine on Day 8 of each cycle), the last dose received to 4 weeks prior Dose 1 of MAGE-A3 ASCI. No additional chemotherapy was administered to patients from Week 0 onwards.

Reporting group title	MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 3 as per protocol summary) consisted in patients aged 18 years or more with completely resected stage IB, II or III tumors who are not due for cis-diaminedichloroplatine (CDDP) + vinorelbine chemotherapy, who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to have had their tumor resected at least 4 to 8 weeks prior to receiving Dose 1 of MAGE-A3 ASCI product and to receive no chemo-/radiotherapy during the entire duration of the study.

Reporting group title	Chemo/radiotherapy-MAGE-A3 ASCI Group

Reporting group description:

This group (Cohort 4 as per protocol summary) consisted in patients aged 18 years or more with unresectable stage III tumors following chemotherapy and radiotherapy who received 8 doses of the GSK1572932A (or MAGE-A3 ASCI) study product. The 8-dose course of MAGE-A3 ASCI study product was to be administered according to a 3-week intervals administration schedule, at Weeks 0, 3, 6, 9, 12, 15, 18 and 21, intramuscularly in the deltoid or lateral region of the thigh, alternating left and right side, irrespective of the patient's body weight or area. Patients were to have received their last dose of chemotherapy (cis-diaminedichloroplatine [CDDP] + vinorelbine [either the generic Vinorelbine®or Pierre Fabre's Navelbine®]) and/or radiotherapy 2 to 6 weeks prior to receiving Dose 1 of MAGE-A3 ASCI product. No additional chemo-/radiotherapy was administered to patients in this cohort from Week 0 onwards.

Serious adverse events	Chemotherapy + MAGE-A3 Group	Chemotherapy/MAGE-A3 ASCI Group	MAGE-A3 ASCI Group
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 19 (63.16%)	0 / 18 (0.00%)	4 / 18 (22.22%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant palate neoplasm			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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
Contusion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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			
Thrombosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			

subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	6 / 19 (31.58%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	5 / 19 (26.32%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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
Mucosal inflammation			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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
Pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			

subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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
Pulmonary embolism			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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
Bronchial haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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			
Hepatic failure			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Urticaria chronic			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
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 and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (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

Serious adverse events	Chemo/radiotherapy -MAGE-A3 ASCI Group		
Total subjects affected by serious			

adverse events			
subjects affected / exposed	3 / 12 (25.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant palate neoplasm			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Thrombosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure acute			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Neutropenia			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Urticaria chronic			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Chemotherapy + MAGE-A3 Group	Chemotherapy/MAGE-A3 ASCI Group	MAGE-A3 ASCI Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 19 (100.00%)	18 / 18 (100.00%)	17 / 18 (94.44%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Malignant palate neoplasm			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Arterial disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Arteriosclerosis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Orthostatic hypotension			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Peripheral coldness			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Phlebitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Phlebitis superficial			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Raynaud’s phenomenon			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Thrombosis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
General disorders and administration site conditions			

Administration site pain			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Administration site reaction			
subjects affected / exposed	4 / 19 (21.05%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Asthenia			
subjects affected / exposed	7 / 19 (36.84%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences (all)	7	0	2
Axillary pain			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	1 / 19 (5.26%)	1 / 18 (5.56%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Chills			
subjects affected / exposed	0 / 19 (0.00%)	4 / 18 (22.22%)	3 / 18 (16.67%)
occurrences (all)	0	4	3
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 19 (26.32%)	5 / 18 (27.78%)	3 / 18 (16.67%)
occurrences (all)	5	5	3
Gait disturbance			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypothermia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	2 / 19 (10.53%)	1 / 18 (5.56%)	5 / 18 (27.78%)
occurrences (all)	2	1	5
Injection site coldness			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			

subjects affected / exposed	0 / 19 (0.00%)	3 / 18 (16.67%)	2 / 18 (11.11%)
occurrences (all)	0	3	2
Injection site haematoma			
subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Injection site inflammation			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	4 / 18 (22.22%)
occurrences (all)	0	0	4
Injection site oedema			
subjects affected / exposed	4 / 19 (21.05%)	2 / 18 (11.11%)	0 / 18 (0.00%)
occurrences (all)	4	2	0
Injection site pain			
subjects affected / exposed	5 / 19 (26.32%)	10 / 18 (55.56%)	12 / 18 (66.67%)
occurrences (all)	5	10	12
Injection site pruritus			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Injection site rash			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	10 / 19 (52.63%)	3 / 18 (16.67%)	2 / 18 (11.11%)
occurrences (all)	10	3	2
Injection site swelling			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 19 (0.00%)	2 / 18 (11.11%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Mucosal inflammation			
subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Oedema			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			

subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Pain			
subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	7 / 19 (36.84%)	6 / 18 (33.33%)	5 / 18 (27.78%)
occurrences (all)	7	6	5
Sense of oppression			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Bronchial haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bronchitis chronic			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	2 / 19 (10.53%)	3 / 18 (16.67%)	2 / 18 (11.11%)
occurrences (all)	2	3	2
Dysphonia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	3 / 19 (15.79%)	1 / 18 (5.56%)	1 / 18 (5.56%)
occurrences (all)	3	1	1
Epistaxis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hiccups			

subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 19 (5.26%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Pleural effusion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pleurisy			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Sputum discoloured			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 19 (5.26%)	2 / 18 (11.11%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Depression			
subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Insomnia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Investigations			
Lymphocyte count decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Urine output decreased			

subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Weight decreased			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Weight increased			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Radiation pneumonitis			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cardiac failure acute			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Cervicobrachial syndrome			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Dysaesthesia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	4 / 19 (21.05%)	5 / 18 (27.78%)	2 / 18 (11.11%)
occurrences (all)	4	5	2
Intercostal neuralgia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 19 (0.00%)	3 / 18 (16.67%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Paraesthesia			
subjects affected / exposed	1 / 19 (5.26%)	3 / 18 (16.67%)	0 / 18 (0.00%)
occurrences (all)	1	3	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Polyneuropathy			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Sinus headache			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	6 / 19 (31.58%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	6	0	0
Febrile neutropenia			
subjects affected / exposed	5 / 19 (26.32%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Monocytosis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	7 / 19 (36.84%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	7	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	1 / 19 (5.26%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Eye disorders			
Periorbital oedema			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Abdominal pain			

subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	7 / 19 (36.84%)	2 / 18 (11.11%)	0 / 18 (0.00%)
occurrences (all)	7	2	0
Diarrhoea			
subjects affected / exposed	5 / 19 (26.32%)	1 / 18 (5.56%)	3 / 18 (16.67%)
occurrences (all)	5	1	3
Flatulence			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorder			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Loose tooth			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	7 / 19 (36.84%)	5 / 18 (27.78%)	1 / 18 (5.56%)
occurrences (all)	7	5	1
Regurgitation			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	6 / 19 (31.58%)	6 / 18 (33.33%)	2 / 18 (11.11%)
occurrences (all)	6	6	2
Hepatobiliary disorders			

Cholecystitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hepatic failure			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Alopecia			
subjects affected / exposed	4 / 19 (21.05%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	4	0	1
Dermatitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Erythema			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Skin discolouration			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Renal failure			

subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Renal pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 19 (15.79%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	3	0	1
Back pain			
subjects affected / exposed	1 / 19 (5.26%)	2 / 18 (11.11%)	3 / 18 (16.67%)
occurrences (all)	1	2	3
Bone pain			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	2 / 19 (10.53%)	3 / 18 (16.67%)	0 / 18 (0.00%)
occurrences (all)	2	3	0
Myalgia			
subjects affected / exposed	3 / 19 (15.79%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	3	1	0
Osteopenia			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Gingivitis			

subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Lobar pneumonia			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Paronychia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 19 (0.00%)	1 / 18 (5.56%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 19 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 19 (15.79%)	2 / 18 (11.11%)	2 / 18 (11.11%)
occurrences (all)	3	2	2
Hypercholesterolaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Hypokalaemia			
subjects affected / exposed	1 / 19 (5.26%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	5 / 19 (26.32%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	5	1	0
Iron deficiency			
subjects affected / exposed	2 / 19 (10.53%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Chemo/radiotherapy -MAGE-A3 ASCI Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 12 (91.67%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant palate neoplasm			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Arterial disorder			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Arteriosclerosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Orthostatic hypotension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Peripheral coldness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Phlebitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Phlebitis superficial			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Raynaud’s phenomenon			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Thrombosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Administration site reaction			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Chills			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Gait disturbance			

subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Hypothermia				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Influenza like illness				
subjects affected / exposed	2 / 12 (16.67%)			
occurrences (all)	2			
Injection site coldness				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site erythema				
subjects affected / exposed	1 / 12 (8.33%)			
occurrences (all)	1			
Injection site haematoma				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site inflammation				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site oedema				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site pain				
subjects affected / exposed	3 / 12 (25.00%)			
occurrences (all)	3			
Injection site pruritus				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site rash				
subjects affected / exposed	0 / 12 (0.00%)			
occurrences (all)	0			
Injection site reaction				
subjects affected / exposed	2 / 12 (16.67%)			
occurrences (all)	2			
Injection site swelling				

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Oedema			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	4 / 12 (33.33%)		
occurrences (all)	4		
Sense of oppression			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bronchial haemorrhage			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Bronchitis chronic			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Cough			

subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hiccups			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Pleurisy			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Sputum discoloured			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Depression			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Investigations			
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Urine output decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Weight increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Radiation pneumonitis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Wound			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Cardiac failure acute			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Cervicobrachial syndrome			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Headache			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Intercostal neuralgia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Nervous system disorder			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Polyneuropathy			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Sinus headache			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Somnolence			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Tremor			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Febrile neutropenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Monocytosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tinnitus			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Eye disorders			
Periorbital oedema			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Abdominal pain upper			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorder			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Loose tooth			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Mouth ulceration			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Regurgitation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hepatic failure			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Erythema			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Skin discolouration			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Renal failure			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Renal pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Bone pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Osteopenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	3		
Gingivitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Lobar pneumonia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Lower respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		
Paronychia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		

Rhinitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		
Iron deficiency subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 March 2009	In Amendment 1, dated 9 March 2009, the following changes were made: 1 /The patient population for Cohorts 1, 2 and 3 was modified from resected stage IB, II or IIIA to completely resected stage IA, IIB or III (with the exception of stage III N2 and N3) to allow enrolment of patients with completely resected T4 primary tumor with satellite lesions in the same lobe (stage IIIB). 2/ The recruitment period was extended to increase the feasibility of the study i.e. to facilitate enrolment and ensure that the targeted number of patients was reached. 3/The inclusion of tissue from lymph nodes as screening material was allowed to enable the screening and enrolment of patients with a less accessible primary tumor, which was especially important for patients in Cohort 4 (i.e. patients with unresectable stage III tumors, for whom no surgical material was obtained). 4/The time window between surgery/previous therapy and the first ASCI administration was extended for 2 cohorts i.e. 4 to 12 weeks for patients in Cohort 1, and 2 to 6 weeks for patients in Cohort 4. 5/The replacement of patients from Cohort 1 who withdrew because of an adverse event resulting from chemotherapy before the first ASCI administration was permitted. 6/ The sections regarding immunological assays were updated to include extension of the immune response analysis with assessment of anti-Cytosine Phosphate Guanosine oligodeoxynucleotide (CpG) antibody responses and analysis of antigen spreading.
06 January 2011	In Protocol Amendment 2, dated 6 January 2011, the following changes were made: 1/The description of the study product was changed to the 2-vial presentation, as the 3-vial presentation was no longer manufactured. 2/The handling instructions were updated to increase the allowed delay and allowed temperature between reconstitution of the study product and administration. 3/ In addition, the sections on the storage of the study product and study contact for reporting SAEs were also updated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
05 August 2013	The study was terminated early on 5 August 2008, due to slow recruitment and difficulties to achieve the required patient population in the cohort 4. Enrolment and study procedures for patients enrolled in the other 3 groups took place as per planned.	-

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

An analysis for anti-CpG immunogenicity was planned but not performed as the related test remains under development & it is not foreseen by GSK Biologicals that this immunogenicity has association with clinical benefit.

Notes: