Clinical trial results:
A two part Phase IIa Study, to Evaluate the Safety and Tolerability, Pharmacokinetics, Proof of Mechanism and Potential for Efficacy of an Anti-IL-7 Receptor- Monoclonal Antibody (GSK2618960) in the Treatment of Primary Sjögren's Syndrome.

Summary

EudraCT number	2016-004258-14
Trial protocol	GB
Global end of trial date	19 September 2017

Results information

Result version number	v1 (current)
This version publication date	30 December 2018
First version publication date	30 December 2018
Summary attachment (see zip file)	Cancelled before Active Statement (Cancelled before Active Statement 201579.doc)

Trial information

Trial identification

Sponsor protocol code	201579

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	980 Great West Road, Brentford, United Kingdom, Middlesex
Public contact	GlaxoSmithKline, GSK Response Center, 1 866-435-7343,
Scientific contact	GlaxoSmithKline, GSK Response Center, 1 866-435-7343,

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	19 September 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 September 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Part I
Assess safety and tolerability of repeat intravenous (IV) administration of GSK2618960.

Part II
Assess safety and tolerability of repeat IV administration of GSK2618960

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 September 2017
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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial

Pre-assignment

Screening details:

NA

Period 1

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

Arms

Arm title	GSK2618960 2 mg/kg

Arm description:

GSK2618960 2 mg/kg

Arm type	Experimental
Investigational medicinal product name	GSK2618960
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosage would have been Part I & II: GSK2618960 2 milligram per kilogram (mg/kg).

Number of subjects in period 1	GSK2618960 2 mg/kg
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Overall Study

Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	99999	99999	
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	0		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	GSK2618960 2 mg/kg
Reporting group description: GSK2618960 2 mg/kg	

Primary: Number of subjects with Adverse Events (AEs): Part 1

End point title	Number of subjects with Adverse Events (AEs): Part 1[1]
End point description: 99999 is "Not applicable" value or 0 participants, this trial was discontinued with no participants enrolled in the trial.	
End point type	Primary
End point timeframe: NA	

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: No subjects were enrolled in the trial hence results are not available

End point values	GSK2618960 2 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: NA	99999			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
All adverse events occurring during the course of the clinical trial were to be collected.	
Adverse event reporting additional description:	
NA	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No subjects were enrolled in the trial hence results are not available

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported