Clinical trial results:
A Phase I/II, randomised, observer-blind, controlled multi-country study to assess the safety, reactogenicity and immunogenicity of a single intramuscular dose of GSK Biologicals' investigational RSV vaccine (GSK3003891A), in healthy pregnant women aged 18 to 40 years and infants born to vaccinated mothers

Summary

EudraCT number	2016-002733-30
Trial protocol	GB ES FI
Global end of trial date	14 July 2017

Results information

Result version number	v1 (current)
This version publication date	05 January 2019
First version publication date	05 January 2019
Summary attachment (see zip file)	Cancelled before Active Statement (Cancelled before Active Statement.pdf)

Trial information

Trial identification

Sponsor protocol code	204810

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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 Disclosure Advisor, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, 44 2089904466, 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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 July 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 July 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

• To evaluate the safety and reactogenicity of a single intramuscular (IM) dose of study vaccine in pregnant women up to 6 months after delivery (Month 6).
• To assess the safety of a single intramuscular (IM) dose of study vaccine in pregnant women, in terms of pregnancy outcomes.
• To evaluate the safety in infants born to mothers who were vaccinated with a single IM dose of study vaccine up to 6 months after birth (Month 6).

Protection of trial subjects:

The study was cancelled before active (see attached statement). No patient entered the study, therefore no results/data are available.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 July 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	Spain: 33333
Country: Number of subjects enrolled	United Kingdom: 33333
Country: Number of subjects enrolled	Finland: 33333
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)	50000
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	49999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99999 is "Not Applicable" value or '0' participants. The study was cancelled before active (see attached statement). No patient entered the study, therefore no results/data are available.

Pre-assignment

Screening details:

The study was cancelled before active (see attached statement).

Period 1

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

Arms

Arm title	No-Arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	RSV vaccine (GSK3003891A) formulation
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

The product was not administered as the study was cancelled before active.

Number of subjects in period 1	No-Arm
Started	99999
Completed	0
Not completed	99999
Study was cancelled before active	99999

Baseline characteristics

End points

End points reporting groups

Reporting group title	No-Arm

Reporting group description: -

Primary: No end point results

End point title	No end point results[1]

End point description:

End point type	Primary

End point timeframe:

The study was cancelled before active (see attached statement).

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 study was cancelled before active (see attached statement).

End point values	No-Arm			
Subject group type	Reporting group			
Number of subjects analysed	99999			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: The study was cancelled before active (see attached statement).	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0

Frequency threshold for reporting non-serious adverse events: 0 %

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: The study was cancelled before active (see attached statement).

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? Yes

Date	Interruption	Restart date
14 July 2017	The study was cancelled before active (see attached statement).	-

Notes:

Limitations and caveats

None reported