



Clinical trial results:

An Open-labelled, Single-arm, Multicentre Clinical Study to Evaluate the Usability and Safety of the Pre-filled Pen and Pre-filled Syringe of SB5 in Subjects with Rheumatoid Arthritis

Summary

EudraCT number	2014-004887-39
Trial protocol	PL
Global end of trial date	08 March 2016

Results information

Result version number	v1 (current)
This version publication date	28 December 2018
First version publication date	28 December 2018

Trial information

Trial identification

Sponsor protocol code	SB5-G21-RA
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02326233
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Samsung Bioepis Co., Ltd.
Sponsor organisation address	107, Cheomdan-daero, Yeonsu-gu, Incheon, Korea, Republic of,
Public contact	Information Desk, Samsung Bioepis Co., Ltd., 82 032 455 3114, bioepisinfo@samsung.com
Scientific contact	Information Desk, Samsung Bioepis Co., Ltd., 82 032 455 3114, bioepisinfo@samsung.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	08 March 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	08 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to demonstrate the comparability between subcutaneous (SC) delivery administration of SB5 via the pre-filled pen (Pen) versus the pre-filled syringe (PFS) in terms of injection site pain in subjects with rheumatoid arthritis (RA).

Protection of trial subjects:

The study and clinical study protocols were reviewed and approved by Independent Ethics Committee (IEC) or Institutional Review Board (IRB).

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (2008) and that are consistent with International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines (ICH E6) and applicable local regulatory requirements and laws.

The nature and purpose of the study was fully explained to each subject and written informed consent was obtained at Screening from each subject before any study related procedures were performed. The consent documents for the study was reviewed and approved by the appropriate IEC or IRB prior to use.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 August 2015
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	Poland: 49
Worldwide total number of subjects	49
EEA total number of subjects	49

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)	49
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Of the 49 subjects enrolled, 48 (98.0%) subjects completed 6 weeks of treatment. Prior to Week 6, one (2.0%) subject withdrew from the study due to withdrawal of consent. These 48 (98.0%) subjects completed the 12 weeks of treatment as well as the study. No subjects withdrew from the study after Week 6.

Pre-assignment period milestones

Number of subjects started	49
Number of subjects completed	49

Period 1

Period 1 title	Open-label, single arm (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	SB5 Pen/PFS
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	SB5
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen, Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

0.8 mL in 50 mg/mL solution for sc injection provided in Pen or PFS. 40 mg sc injection via PFS at Week 0 and Week 2 and then 40 mg sc injection via Pen st Week 4 and then every other week thereafter up to Week 10.

Number of subjects in period 1	SB5 Pen/PFS
Started	49
Completed	48
Not completed	1
Consent withdrawn by subject	1

Baseline characteristics

Reporting groups

Reporting group title	Open-label, single arm
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Reporting group description: -

Reporting group values	Open-label, single arm	Total	
Number of subjects	49	49	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	49	49	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	40.9		
standard deviation	± 9.08	-	
Gender categorical			
Units: Subjects			
Female	39	39	
Male	10	10	

End points

End points reporting groups

Reporting group title	SB5 Pen/PFS
Reporting group description: -	

Primary: The change in injection site pain score using an 11-point visual numeric scale

End point title	The change in injection site pain score using an 11-point visual numeric scale ^[1]
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End point description:

End point type	Primary
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End point timeframe:

Difference of injection site pain score (Week 6 - Week 2)

Notes:

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

Justification: There is only one group (SB5 PFS then change to SB5 Pen) therefore it is impossible to enter values in statistical methods page (At least two comparison groups are needed to proceed entering the page). Equivalence between two dosing regimens was declared if the 97.5% confidence interval (CI) of the difference in the injection site pain score was entirely contained within the equivalence margin of ± 5 with pre-defined alpha level of 0.025 for both the timepoints, i.e. overall alpha level was 0.05.

End point values	SB5 Pen/PFS			
Subject group type	Reporting group			
Number of subjects analysed	49			
Units: Difference				
number (confidence interval 97.5%)				
Immediately post-injection	-0.35 (-0.99 to 0.30)			
15-30min post-injection	-0.11 (-0.47 to 0.25)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

20 weeks

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.0
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Reporting groups

Reporting group title	SB5 PFS/Pen
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Reporting group description: -

Serious adverse events	SB5 PFS/Pen		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	SB5 PFS/Pen		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 49 (8.16%)		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 49 (8.16%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 December 2014	Administrative change: 11-point numeric rating scale was changed to 11-point visual numeric scale with other administrative changes and editorial changes

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported