Clinical trial results:
SINGLE AGENT JNJ-56022473 IN MDS AND AML PATIENTS FAILING HYPOMETHYLATING AGENT BASED THERAPY

Summary

EudraCT number	2016-000327-10
Trial protocol	DE FR
Global end of trial date	31 October 2018

Results information

Result version number	v1 (current)
This version publication date	29 December 2019
First version publication date	29 December 2019

Trial information

Trial identification

Sponsor protocol code	SAMBA

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02992860
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GWT-TUD GmbH
Sponsor organisation address	Freiberger Straße 33, Dresden, Germany, 01067
Public contact	Medical Consulting, GWT-TUD GmbH, +49 35125933193, martin.puttrich@gwtonline.de
Scientific contact	Medical Consulting, GWT-TUD GmbH, +49 35125933193, martin.puttrich@gwtonline.de

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	25 October 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 July 2018
Global end of trial reached?	Yes
Global end of trial date	31 October 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of JNJ-56022473 for the treatment of MDS and AML patients who have relapsed after or are refractory to treatment with HMAs

Protection of trial subjects:

The conduct, evaluation, and documentation of this study, was in compliance with the Good Clinical Practice Guidelines and under the guiding principles detailed in the Declaration of Helsinki. The study was also be carried out in keeping with applicable local law(s) and regulation(s).
No further specific measures had to be put in place, because it had been assumed, that 9 mg/kg every 14 days is a well tolerated dose and would be the lowest dose that provides adequate exposure and sustained target saturation at the site of action throughout the entire dosing interval.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 November 2016
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	Germany: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	0
From 65 to 84 years	23

85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at 6 study sites in Germany, whereas only 4 sites recruited patients into the study. From November 2016 on a total of 24 patients had been included in the study and treated with study medication before it was prematurely terminated.

Pre-assignment

Screening details:

Screening period started with the patients consent and must completed within 28 days prior initiation of study treatment. Out of 28 screened patients 3 patient became a screening failure and 1 patient have had an SAE prior start of treatment.

Period 1

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

Arms

Arm title	Talacotuzumab

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Talacotuzumab
Investigational medicinal product code	
Other name	JNJ-56022473
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

9 mg / kg body weight every two weeks

Number of subjects in period 1	Talacotuzumab
Started	24
Completed	10
Not completed	14
Adverse event, serious fatal	6
Consent withdrawn by subject	2
Physician decision	1
Adverse event, non-fatal	1
Lack of efficacy	4

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	24	24	
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)	0	0	
From 65-84 years	23	23	
85 years and over	1	1	
Gender categorical Units: Subjects			
Female	7	7	
Male	17	17	

End points

End points reporting groups

Reporting group title	Talacotuzumab

Reporting group description: -

Primary: Overall hematological response rate at 3 months

End point title	Overall hematological response rate at 3 months[1]

End point description:

All patients with one of the following response states at the 3 months response assessment (V6) are defined as responder:
•Complete remission (CR), Partial remission (PR), marrow CR, Stable disease (SD) for MDS or
•Hematologic improvement for MDS or
•CR, Complete remission with incomplete recovery (CRi), morphologic leukemia free state, PR, Cytogenetic complete remission (CRc), Molecular complete remission (CRm), SD for AML

End point type	Primary

End point timeframe:

at 3 months (week 11)

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: As the study had been terminated prematurely, no formal statistical analysis on study endpoints was performed. Available data were only listed and summarized descriptively.

End point values	Talacotuzumab			
Subject group type	Reporting group			
Number of subjects analysed	24			
Units: number of patients	24			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The observation phase for AEs started with signing the informed consent form and ended 28 days after the last intake of study drug, unless the investigator suspects a delayed adverse reaction to the study drug.

Adverse event reporting additional description:

In case of ongoing AEs after the last follow-up visit – especially when related to treatment with the study medication – the respective AE has been followed until resolution, if possible.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	Talacotuzumab

Reporting group description: -

Serious adverse events	Talacotuzumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 24 (100.00%)		
number of deaths (all causes)	11		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 2		
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infusion related infection			
subjects affected / exposed	4 / 24 (16.67%)		
occurrences causally related to treatment / all	3 / 4		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			

subjects affected / exposed	2 / 24 (8.33%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Vascular disorders			
Superior vena cava syndrome			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Thrombosis			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Acute myocardial infarction			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pericardial effusion			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebral infarction			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Blood and lymphatic system disorders			
Anemia			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Disease progression			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General physical health deterioration			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Drug hypersensitivity			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			

subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastrointestinal angiectasia			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal hemorrhage			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Ulcer			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atypical pneumonia			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		

Decice related infection				
subjects affected / exposed	1 / 24 (4.17%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	2 / 24 (8.33%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Escherichia infection				
subjects affected / exposed	1 / 24 (4.17%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Neutropenic infection				
subjects affected / exposed	2 / 24 (8.33%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	6 / 24 (25.00%)			
occurrences causally related to treatment / all	2 / 6			
deaths causally related to treatment / all	1 / 3			
Pneumonia fungal				
subjects affected / exposed	2 / 24 (8.33%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonia staphylococcal				
subjects affected / exposed	1 / 24 (4.17%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	4 / 24 (16.67%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 3			
Staphylococcal infection				

subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Diabetic hyperglycaemic coma			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Talacotuzumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 24 (100.00%)		
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Haematoma			
subjects affected / exposed	5 / 24 (20.83%)		
occurrences (all)	6		
Hypertension			

subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Pallor			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Phlebitis			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Surgical and medical procedures			
Temporomandibular joint surgery			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Chest discomfort			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Chest pain			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Chills			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences (all)	3		
Fatigue			
subjects affected / exposed	5 / 24 (20.83%)		
occurrences (all)	5		
Feeling hot			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Infusion site erythema			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Injection site erythema			

subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Mucosal haemorrhage			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Mucosal inflammation			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Oedema			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Oedema peripheral			
subjects affected / exposed	4 / 24 (16.67%)		
occurrences (all)	4		
Pain			
subjects affected / exposed	4 / 24 (16.67%)		
occurrences (all)	5		
Peripheral swelling			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	7 / 24 (29.17%)		
occurrences (all)	19		
Sinusitis			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Immune system disorders			
Decreased immune responsiveness			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Reproductive system and breast disorders			

Testicular oedema			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Vaginal haemorrhage			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	5 / 24 (20.83%)		
occurrences (all)	5		
Dyspnoea exertional			
subjects affected / exposed	4 / 24 (16.67%)		
occurrences (all)	4		
Epistaxis			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences (all)	3		
Pleural effusion			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Stridor			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Disorientation			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Blood glucose decreased			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Blood glucose increased			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
C-reactive protein increased			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Fall			
subjects affected / exposed	4 / 24 (16.67%)		
occurrences (all)	4		
Infusion related reaction			
subjects affected / exposed	4 / 24 (16.67%)		
occurrences (all)	7		
Wound haematoma			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Tachyarrhythmia			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Tachycardia			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences (all)	3		
Nervous system disorders			

Dizziness subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Paraparesis subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Phantom pain subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	4 / 24 (16.67%) 4		
Neutropenia subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Splenomegaly subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Eye disorders Visual impairment subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1		
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	4 / 24 (16.67%) 4		
Constipation subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2		
Diarrhoea subjects affected / exposed occurrences (all)	7 / 24 (29.17%) 7		
Dysphagia			

subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Gingival bleeding			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Intra-abdominal haematoma			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Lip swelling			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Mouth ulceration			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences (all)	5		
Stomatitis			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Tongue discolouration			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	2		

Petechiae			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Rash			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Hydronephrosis			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Urinary incontinence			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	2		
Back pain			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	12		
Muscle tightness			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	3		
Pathological fracture			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Infections and infestations			

Aspergillus infection			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Pneumonia			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences (all)	3		
Sepsis			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	4		
Wound sepsis			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Dehydration			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Hyperkalaemia			

subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Hypoglycaemia			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	2		
Hypokalaemia			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences (all)	3		
Type 3 diabetes mellitus			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Vitamin D deficiency			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 February 2017	Version 3.0 dated 10 Jan 2017 was issued to include new information from the updated safety reference document.
13 September 2017	Version 5.0 dated 28 Jul 2017 was issued to adjust the section "drug administration" according to updated safety information.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Recruitment was stopped in July 2017 due to results from a pivotal study which indicated added toxicity and lack of efficacy of talacotuzumab.

Notes: