CLINICAL SERIOUS ADVERSE EVENT (*) REPORT
Janssen Research & Development, LLC **FAX COVER PAGE**

Protocol Number: 56022473MDS2002 EUDRACT Number: (if applicable) 2016-003328-22

To: Lies Vanheeswijck Fax No: 0800 0200 010

Pages: ☐ Initial report ☐ Follow-up report ☐ Additional/New to previous term ☐ Update of previous term (*Specify in the narrative section what term has been updated)*

Date of Report: d d M O N y y

SITE INFORMATION

Site ID Number NL10003 Subject ID Number:

Country where SAE occurred:

Date Investigator/Investigational Staff became aware of SAE: d d M O N y y

Principal Investigator's Name: First **G. H.** Last: **Huls** Reported By: First Name: Last Name:

Site Address: **UMCG – H anzeplein 1 - 9713 GZ Groningen**

Telephone #: (country code) Fax #: (country code)

E-mail Address: ……..

REPORTING

Investigator's Statement (Principal or Sub-Investigator)

I have verified the data on this Clinical SAE Report and have determined they are accurate and compatible with source documents.

Investigator Name (Please print): First: Last:

Investigator Signature/e-Signature (required): _____ Date: d d M O N y y

FOR SPONSOR USE ONLY

Date Clinical SAE Report received: d d M O N y y

GMS Reference Number:

Sponsor Rep/Agent who received this report: (*please print name clearly)*

Clinical Contact's Telephone Number, please include country code:

Additional information requested? ☐ No ☐ Yes, specify:

(*) For a Clinical Trial investigating a Combination Product, the term 'Serious Adverse Event' will also include Unanticipated (Serious) Adverse Device Effect and fields related to the device constituent must be completed

Investigator: File original SAE report in Trial Center File (TCF).
Sponsor: File a copy of the SAE report in the Investigator File with a copy of the attachments.

SAE DESCRIPTION

Attach SAE CRF Pages relevant to the SAE and select the checkbox below:

☐SAE CRF ☐Concomitant Therapy ☐Medical History ☐Exposure/Study Drug Administration ☐ Other:

Investigator Narrative: For each SAE describe below the course of events (e.g., duration of signs/symptoms, sequelae of SAE, device malfunction), timing and suspected causes. Include the total number of study doses received during the entire course of the trial, risk factors, investigations and relevant supporting diagnostics (e.g., labs), differential diagnosis, treatment for SAE/ response to treatment, and other relevant comments.

Adverse Events of Special Interests (AEoSI):	If applicable, this information can be added as an optional field (delete if not applicable) Adverse Event of Special Interest (Serious) ☐ Yes ☐ No Adverse Event of Special Interest (Non-Serious) ☐ Yes ☐ No
Dechallenge	If applicable, describe whether and which event(s) abated on withdrawal of the study agent(s).
Rechallenge	If applicable, describe whether and which event(s) re-occurred on re-initiation of the study agent(s).

Investigator: File original SAE report in TCF.
Sponsor: File a copy of the SAE report in the Investigator File with a copy of the attachments.

CLINICAL SERIOUS ADVERSE EVENT REPORT

☐ Initial Report ☐ Follow-up report | Subject ID Number:

SUBJECT

Sex: ☐ Male ☐ Female ☐ Undifferentiated

Height: ☐ cm ☐ in

Weight: ☐ kg ☐ lb.

Age at Onset of SAE ☐ Days ☐ Months ☐ Years

SAE DIAGNOSIS

*If this is a follow-up report, please indicate for each SAE, whether the SAE Diagnosis provided is **replacing** the initial diagnosis, or if the SAE Diagnosis is a new term, reported **in addition to** the SAE Term(s) reported in the initial report.*

	SAE (if diagnosis unknown, list symptoms)	**SAE** (if diagnosis unknown, list symptoms)	**SAE** (if diagnosis unknown, list symptoms)
Onset	d d M O N y y 24 hour clock	d d M O N y y 24 hour clock	d d M O N y y 24 hour clock
Severity[1]	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe	☐ Mild ☐ Moderate ☐ Severe

	Causality	**Action taken with agent**	**Causality**	**Action taken with agent**	**Causality**	**Action taken with agent**
Talacotuzumab	☐ Not related ☐ Related	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Related	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Related	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
Daratumumab	☐ Not related ☐ Related	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Related	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Related	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable

Related to Trial Procedure?

Is SAE related to any trial procedure **not** including study agent therapy? If yes, please specify the specific trial procedure in the narrative

☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes

Related to Device?

Is SAE related to the device constituent of the Combination Product? If yes, please include in narrative
For a Product Malfunction, TV-FRM-03237 Product Quality Complaint Form is completed by the Sponsor/Representative

☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes

SAE Outcome

☐ Recovered/resolved ☐ Recovered/resolved with sequelae ☐ Recovering/resolving ☐ Not recovered/not resolved ☐ Fatal[1] ☐ Unknown Recovery date: d d M O N y y	☐ Recovered/resolved ☐ Recovered/resolved with sequelae ☐ Recovering/resolving ☐ Not recovered/not resolved ☐ Fatal[1] ☐ Unknown Recovery date: d d M O N y y	☐ Recovered/resolved ☐ Recovered/resolved with sequelae ☐ Recovering/resolving ☐ Not recovered/not resolved ☐ Fatal[1] ☐ Unknown Recovery date: d d M O N y y

[1] Alternative NCI Toxicity Grading and/or NCI Common Terminology Criteria can be used if applicable.

SAE Seriousness Category						
	☐ Death[2]	☐ Persistent or significant disability/incapacity	☐ Death[2]	☐ Persistent or significant disability/incapacity	☐ Death[2]	☐ Persistent or significant disability/incapacity
	☐ Hospitalization required[3]	☐ Congenital anomaly/ birth defect	☐ Hospitalization required[3]	☐ Congenital anomaly/ birth defect	☐ Hospitalization required[3]	☐ Congenital anomaly/ birth defect
	☐ Prolonged hospitalization	☐ Other medically important condition	☐ Prolonged hospitalization	☐ Other medically important condition	☐ Prolonged hospitalization	☐ Other medically important condition
	☐ Life threatening	☐ Serious Injury/Death possibly caused by Device Malfunction	☐ Life threatening	☐ Serious Injury/Death possibly caused by Device Malfunction	☐ Life threatening	☐ Serious Injury/Death possibly caused by Device Malfunction
		☐ Required medical or surgical intervention to prevent permanent impairment or damage (Device Only)		☐ Required medical or surgical intervention to prevent permanent impairment or damage (Device Only)		☐ Required medical or surgical intervention to prevent permanent impairment or damage (Device Only)

[1] If the SAE outcome is "Fatal", please ensure that the "Death" checkbox in the "SAE Seriousness Category" section is marked.
[2] Record death information on the following page in the "SAE General" section. [3] Record hospital admission date on the following page in the "Hospital" section.

Continue on next page

CLINICAL SERIOUS ADVERSE EVENT REPORT (continued)

☐ Initial Report ☐ Follow-up report | Subject ID Number:

Death

Date of death*: d d M O N y y

Was autopsy performed?

☐ No ☐ Yes (If yes, attach copy of report if available)

Hospital

Hospital admission date: d d M O N y y

Hospital discharge date: d d M O N y y

Trial Design

☐ Open-label only
☐ Blinded only
☐ Multi-phased: ☐ Open-label phase ☐ Blinded phase

If blinded trial or blinded phase of trial:

Random. No:

Blind broken?
☐ No
☐ Yes**

STUDY PRODUCT(S) AND DOSING

☐ **Subject has NEVER received any study agent (skip remainder of this section)**

Start Date	Start Time	Stop Date	Stop Time	Indication
d d M O N y y	24 hour clock	d d M O N y y	24 hour clock	

Agent A	Batch/Lot No.	Med. Kit No.

Dose	Unit	Frequency	Route

Device Name (For Combination Product)	Batch/Lot No.	Expiry Date

Start Date	Start Time	Stop Date	Stop Time	Indication
d d M O N y y	24 hour clock	d d M O N y y	24 hour clock	

Agent B	Batch/Lot No.	Med. Kit No.

Dose	Unit	Frequency	Route

Device Name (For Combination Product)	Batch/Lot No.	Expiry Date

* Ensure this Date of death is entered on the 'End of Trial' (Death information) or other disposition page in the subject's CRF.
** If blind broken, ensure that 'Date randomization code was broken' is entered on the appropriate CRF page.

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