CLINICAL SERIOUS ADVERSE EVENT REPORT

Janssen Research and Development, LLC **FAX COVER PAGE**

Protocol Number: 54767414AMY3001 EUDRACT Number: (if applicable) 2016-001737-27

To: Fax No:

Pages: ☐ Initial report ☐ Follow-up report Date of Report: d d M O N y y

SITE INFORMATION

Site ID Number 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 Last: Reported By: First Name: Last Name:

Site Address:

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

E-mail Address:

REPORTING

Investigator's Statement (Principal or Sub-Investigator)

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

Investigator Name (Please print): First: Last:

Investigator Signature (required): Date: d d M O N y y

FOR SPONSOR USE ONLY

Date 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:

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.

SAE DESCRIPTION

ATTACH SAE CRF PAGES AND COPIES OF OTHER RELEVANT CRF PAGES/DOCUMENTS AND INDICATE IN CHECKBOXES BELOW:

☐SAE CRF ☐Concomitant Therapy ☐Medical History ☐Exposure/Study Drug Administration ☐Relevant Labs, X-rays

☐ Other:

Investigator Narrative: For **EACH SAE** describe the course of events, timing and suspected causes

Signs & Symptoms	
Risk Factors	
Investigations and Supporting Diagnostics (eg labs)	
Differential Diagnosis	
Course of Events	
Treatment for SAE/ Response to Treatment	
Suspected Causes	
Other Comments	
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	**Weight:** ☐ kg ☐ lb	**Date of Birth:** d d M O N y y y y	**Age at Onset of SAE**

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
Toxicity grade	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 (NCI-CTCAE grades ver. 4.03)	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 (NCI-CTCAE grades v. 4.03)	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 (NCI-CTCAE grades v. 4.03)

	Causality	Action taken with agent	Causality	Action taken with agent	Causality	Action taken with agent
Agent A Daratumumab	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
Agent B Cyclophosphamide	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
Agent C Bortezomib	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
Agent D Dexamethasone	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ 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 narrative

☐ No ☐ Yes	☐ No ☐ Yes	☐ No ☐ Yes

SAE Outcome	☐ Recovered/resolved ☐ Recovered/resolved with sequelae Recovery date: __ __ | __ __ __ | __ __ (d d | M O N | y y) ☐ Recovering/resolving ☐ Not recovered/not resolved ☐ Fatal[1] ☐ Unknown	☐ Recovered/resolved ☐ Recovered/resolved with sequelae Recovery date: __ __ | __ __ __ | __ __ (d d | M O N | y y) ☐ Recovering/resolving ☐ Not recovered/not resolved ☐ Fatal[1] ☐ Unknown	☐ Recovered/resolved ☐ Recovered/resolved with sequelae Recovery date: __ __ | __ __ __ | __ __ (d d | M O N | y y) ☐ Recovering/resolving ☐ Not recovered/not resolved ☐ Fatal[1] ☐ Unknown
SAE Seriousness Category	☐ Death[2] ☐ Hospitalization required[3] ☐ Prolonged hospitalization ☐ Life threatening ☐ Persistent or significant disability/incapacity ☐ Congenital anomaly/ birth defect ☐ Other medically important condition	☐ Death[2] ☐ Hospitalization required[3] ☐ Prolonged hospitalization ☐ Life threatening ☐ Persistent or significant disability/incapacity ☐ Congenital anomaly/ birth defect ☐ Other medically important condition	☐ Death[2] ☐ Hospitalization required[3] ☐ Prolonged hospitalization ☐ Life threatening ☐ Persistent or significant disability/incapacity ☐ Congenital anomaly/ birth defect ☐ Other medically important condition

[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 “SAE General” 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)

Hosp

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

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.
Daratumumab		

Dose	Unit	Frequency	Route

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

Agent B	Batch/Lot No.
Cyclophosphamide	

Dose	Unit	Frequency	Route

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 C	Batch/Lot No.
Bortezomib	

Dose	Unit	Frequency	Route

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 D		Batch/Lot No.		
Dexamethasone				
Dose		Unit	Frequency	Route

* Ensure this Date of death is entered on the 'End of Trial' (Death information) or other disposition page in the subject's CRF.

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