CLINICAL SERIOUS ADVERSE EVENT REPORT
Janssen Research and Development, LLC

FAX COVER PAGE

Protocol Number: PCI-32765MCL3002

EUDRACT Number: (if applicable) 2012-004056-11

To: Lies Vanheeswijck

Fax No: 0800 0200010

Pages: ______ ☐ Initial report ☐ Follow-up report

Date of Report: d d M O N y y

SITE INFORMATION

Site ID Number 310001

Subject ID Number: ______

Country where SAE occurred: The Netherlands

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

Principal Investigator's Name: Drs. M. Nijland

Reported By: ______

Site Address: UMCG Groningen

Telephone #: ______ (country code)

Fax #: ______ (country code)

**(Dummy) initials to be removed by GTM/LTM for trials where study subjects will be identified by the Subject ID and Date of Birth (DOB).*

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): ______

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).

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CLINICAL SERIOUS ADVERSE EVENT REPORT

☐ Initial Report ☐ Follow-up report

Subject ID Number:

SUBJECT

Sex:	Height:	Weight:	Date of Birth:	Age at Onset of SAE
☐ Male ☐ Female ☐ Undifferentiated	☐ cm ☐ in	☐ kg ☐ lb	d d M O N y y y y	☐ 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.*
** (Dummy) initials to be removed by GTM/LTM for trials where study subjects will be identified by the Subject ID and Date of Birth (DOB).*

	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/Grading	☐ Mild (Grade1) ☐ Moderate (Grade 2) ☐ Severe (Grade 3) ☐ Life threatening/Disabling (Grade 4) ☐ Death (Grade5)		☐ Mild (Grade1) ☐ Moderate (Grade 2) ☐ Severe (Grade 3) ☐ Life threatening/Disabling (Grade 4) ☐ Death (Grade5)		☐ Mild (Grade1) ☐ Moderate (Grade 2) ☐ Severe (Grade 3) ☐ Life threatening/Disabling (Grade 4) ☐ Death (Grade5)	
	Causality	**Action taken with agent**	**Causality**	**Action taken with agent**	**Causality**	**Action taken with agent**
Agent PCI-32765/Placebo	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose not changed ☐ Unknown ☐ Not applicable
Agent Rituximab	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose not changed ☐ Unknown ☐ Not applicable
Agent Bendamustine	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ Dose not changed ☐ Unknown ☐ Not applicable	☐ Not related ☐ Doubtful ☐ Possible ☐ Probable ☐ Very likely	☐ Drug withdrawn ☐ Drug interrupted ☐ Dose reduced ☐ 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:

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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 | 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 AGENT(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 PCI-32765	Batch/Lot No.	Med. Kit No.

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 Rituximab	Batch/Lot No.	Med. Kit No.

Dose	Unit	Frequency	Route

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

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

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.
** If blind broken, ensure that 'Date randomization code was broken' is entered on the appropriate CRF page.

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