(S)AE instructie MILLENIUM, C16011

Local Investigator:	Prof. Dr. E. Vellenga	
Onderzoeksverpleegkundige:	Miriam Gelderloos	tel: **42379**
Datamanager:	Machteld van der Weg	tel: **45410**

- Iedere SAE dient **binnen 24 uur** na kennisgeving van de SAE **gemeld** te worden aan de sponsor/opdrachtgever.
- Invul instructies te vinden op de G schijf:
  G:\Hematologie Studie\2. Industrie studies\C16011\4.Studie-infomap
- Vul ieder SAE formulier direct en zo zorgvuldig mogelijk in (probeer bij de eerste melding kort, bondig en stellig te formuleren en aannames te vermijden).
- Breng betrokkenen (Local Investigator, onderzoeksverpleegkundige of datamanager) op de hoogte van de SAE melding.
- Het originele SAE formulier dient in de patiëntstatus te worden gearchiveerd.

Op werkdagen kan voor het invullen altijd ondersteuning worden gevraagd aan de (vervanger van de) research-verpleegkundige of datamanager.

FAX: (0) 001-202-315-3560

MAIL: Takedaoncocases@congnizant.com

- Fax de SAE pagina's en alle aanvullende informatie binnen 24 uur

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MILLENNIUM PHARMACEUTICALS, INC.

Serious Adverse Event & Adverse Event of Special Interest Notification Form

Fax Cover Sheet

To:	Cognizant
Fax No.	United States and Canada: 1-800-963-6290 Rest of World: 1-202-315-3560
From:	Name:
	Phone:
Date:	
Total pages transmitted (including cover sheet):	
Protocol #	

Patient Number: ____ ____ ____ ____ ____ – ____ ____ ____

Patient Initials: ____ ____ ____

Principal Investigator: _____

☐ This is the initial submission

☐ This is follow-up information

Comments:

FAX WITHIN 1 WORKING DAY OF BECOMING AWARE OF THE EVENT.

Version: 05Feb2014

Takeda MILLENNIUM
THE TAKEDA ONCOLOGY COMPANY

Serious Adverse Event Form

Protocol # C16011
Site # 36003
Subject Identifier: ____
Subject Initials: ____

Investigator Information		Patient Information	
Date of report: ___/___/___ (dd mmm yyyy)	Report type: ○ Initial ○ Follow-up	Date of birth ___/___/___ (dd mmm yyyy)	Race: ○ White ○ Black ○ Hispanic ○ American Indian or Alaskan Native ○ Asian or Pacific Islander ○ Other____
Principal Investigator's Name: E.Vellenga	Tel. # (+31) 50 3615410	Gender: ❑ Male ❑ Female	
Principal Investigator's Address: Hanzeplein 1, 9713 GZ Groningen, the Netherlands	Fax # (+31) 3615985	Height: ____ cm /or ____ in	
	Email: hematologiestudie@umcg.nl	Weight: ____ kg /or ____ lb	

Study Drug Information

Indication for use: MM		Indication diagnosis date:
Study drug name: MLN 9708	Regimen:	Action taken with study drug (check all that apply): ○ Dose continued unchanged ○ Dose increased. Date increased: ___/___/___ (dd mmm yyyy) ○ Dose delayed. Date held: ___/___/___ ○ Dose reduced. Date decreased: ___/___/___ ○ Discontinued permanently due to this SAE. Date: ___/___/___ ○ Not applicable, patient no longer receiving study drug.
Date of first dose: ___/___/___ (dd mmm yyyy)	Dose: (i.e. mg, mg/m²)	
Last dose prior to event:: ___/___/___ (dd mmm yyyy) and Cycle____, Day____ (if applic.)	Route: Lot #:	

Study Drug Information (if combination drug)

Study drug name:	Regimen:	Action taken with study drug (check all that apply): ○ Dose continued unchanged ○ Dose increased. Date increased: ___/___/___ (dd mmm yyyy) ○ Dose delayed. Date held: ___/___/___ ○ Dose reduced. Date decreased: ___/___/___ ○ Discontinued permanently due to this SAE. Date: ___/___/___ ○ Not applicable, patient no longer receiving study drug.
Date of first dose: ___/___/___ (dd mmm yyyy)	Dose: (i.e. mg, mg/m²)	
Date of last dose prior to event:: ___/___/___ (dd mmm yyyy) & Cycle____, Day____ (if applic.)	Route: Lot #:	
Study drug name:	Regimen:	Action taken with study drug (check all that apply): ○ Dose continued unchanged ○ Dose increased. Date increased: ___/___/___ (dd mmm yyyy) ○ Dose delayed. Date held: ___/___/___ ○ Dose reduced. Date decreased: ___/___/___ ○ Discontinued permanently due to this SAE. Date: ___/___/___ ○ Not applicable, patient no longer receiving study drug.
Date of first dose: ___/___/___ (dd mmm yyyy)	Dose: (i.e. mg, mg/m²)	
Date of last dose prior to event:: ___/___/___ (dd mmm yyyy) & Cycle____, Day____ (if applic.)	Route: Lot #:	
Study drug name:	Regimen:	Action taken with study drug (check all that apply): ○ Dose continued unchanged ○ Dose increased. Date increased: ___/___/___ (dd mmm yyyy) ○ Dose delayed. Date held: ___/___/___ ○ Dose reduced. Date decreased: ___/___/___ ○ Discontinued permanently due to this SAE. Date: ___/___/___ ○ Not applicable, patient no longer receiving study drug.
Date of first dose: ___/___/___ (dd mmm yyyy)	Dose: (i.e. mg, mg/m²)	
Date of last dose prior to event:: ___/___/___ (dd mmm yyyy) & Cycle____, Day____ (if applic.)	Route: Lot #:	

Study contact completing form ________ Initials ________ Date (dd/mmm/yyyy)

Investigator ________ Initials ________ Date (dd/mmm/yyyy)

Protocol # C16011
Site # 36003
Subject Identifier: _____
Subject Initials: _____

MILLENNIUM
THE TAKEDA ONCOLOGY COMPANY

Serious Adverse Event Form

If more than one serious adverse event, please copy this page and complete all fields on page individually for each SAE

Serious Adverse Event: _____

SAE onset date: ____/____/____ (dd / mmm / yyyy)

Serious Criteria (check all that apply):
- ☐ Death
- ☐ Life threatening
- ☐ Hospitalization / prolonged hospitalization
- ☐ Persistent or significant disability / incapacity
- ☐ Congenital anomaly / birth defect
- ☐ Important medical event

Maximum Intensity:
- ○ Grade 1
- ○ Grade 2
- ○ Grade 3
- ○ Grade 4
- ○ Grade 5

Did SAE(s) abate after stopping study drug? ☐ Yes ☐ No ☐ NA

Did SAE(s) reappear after reintroducing study drug? ☐ Yes ☐ No ☐ NA

Status of SAE at time of this report:

○ Fatal ____/____/____ (dd / mmm / yyyy)

○ Completely resolved ____/____/____ (dd / mmm / yyyy)

○ Resolved with sequelae ____/____/____ (dd / mmm / yyyy)

○ Not completely resolved
- ○ ongoing and unchanged
- ○ ongoing with increased intensity
- ○ ongoing with decreased intensity

Study Drug	Is there a reasonable possibility that the event is associated with this study medication?
1. _____	○ Yes ○ No
2. _____	○ Yes ○ No
3. _____	○ Yes ○ No
4. _____	○ Yes ○ No

Is there a reasonable possibility that the event is associated with:

☐ Non-study drug, procedure, or therapy *Specify:* _____

☐ Another alternative etiology (e.g. indication for use, intercurrent illness) *Specify:* _____

☐ Protocol design or procedures (alone or in addition to study drug) *Specify:* _____

Relevant Laboratory and Diagnostic Tests (Please provide relevant data below or attach **anonymized** copies of reports if available)

Test	Date (dd / mmm / yyyy)	Value / Units	or	Results
	____/____/____			
	____/____/____			
	____/____/____			
	____/____/____			

Study contact completing form _____ Initials _____ Date (dd/mmm/yyyy)

Investigator _____ Initials _____ Date (dd/mmm/yyyy)

Protocol # C16011
Site # 36003
Subject # _____
Subject Initials: _____

MILLENNIUM
THE TAKEDA ONCOLOGY COMPANY

Serious Adverse Event Form

Description of Serious Adverse Event(s)

Please provide a brief narrative description of the SAE (presenting symptoms, clinical course, treatment, etc.), or attach extra pages e.g. hospital discharge summary, if available.

Medical history, Prior therapy, and Concomitant Medications

Please provide or attach *anonymized* relevant data regarding:

- Medical History
- History of Therapy and Events Related to Disease Under Study
- Concomitant Medication

Death Information

Date of death: _____/_____/_____
dd mmm yyyy

Autopsy performed? ❑ Yes ❑ No

If yes, autopsy report attached? ❑ Yes ❑ No

Cause(s) of death (list primary cause of death first):

_____

_____

_____

Was the patient's death related to:

Study drug(s)? ❑ Yes ❑ No If yes, please specify all that apply _____

_____

Protocol design or procedures (alone or in addition to study drug)? ❑ Yes ❑ No If yes, please specify _____

_____

Study contact completing form printed name	Study contact completing form signature	Date (dd/mmm/yyyy)
Investigator printed name	Investigator signature	Date (dd/mmm/yyyy)

Description of Serious Adverse Event(s): *continuation*

Please provide a brief narrative description of the SAE (presenting symptoms, clinical course, treatment, etc.), or attach extra pages e.g. hospital discharge summary, if available.

Medical history, Prior therapy, and Concomitant Medications: *Continuation*

Please provide or attach *anonymized* relevant data regarding:

Medical History; History of Therapy and Events Related to Disease Under Study; Concomitant Medication