SAE instructie B1931022, Ino-Vate
Sponsor: Pfizer

Local Investigator:	Dr. M.Bellido	
Onderzoeksverpleegkundige:	Miriam Gelderloos	tel: **42379** (b.g.g. pieper 77070)
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.
- 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 en datamanager) op de hoogte van de SAE melding.
- Lever het originele ingevulde SAE formulier na het faxen in bij het Trialbureau Hematologie (HP DB21)
Op werkdagen kan voor het invullen altijd ondersteuning worden gevraagd aan de (vervanger van de) researchverpleegkundige en datamanager.
-Geboortedatum patiënt: 01-01-geboortejaar
- Initialen patiënt HG……. (A voor patiënt nummer 1, B voor 2 enz.)

FAX: (0) 001 866 997 8322

- Fax de SAE pagina's en alle aanvullende informatie binnen 24 uur
- Bij vragen bellen naar (0) 001 800 752 9737 (vs)

Pfizer Inc.
150 East 42nd Street, New York, NY 10017
Telephone: (800) 752-9737; Fax: (866) 997-8322

To: Pfizer U.S. Clinical Trial, Drug Safety and Surveillance	
Fax Number: 866-997-8322	Total # Of Pages (including cover sheet):
From (Investigators name): Dr. M. Bellido	Center Contact Name:
Center Contact Phone: +31 50 361 61 61	Center Contact Fax: +31 50 361 59 85

This Fax cover sheet MUST be attached with the completed SAE Form. Please do not reuse any previously-submitted forms or send source documents (e.g. hospital records, lab records, etc.) unless requested with the newly completed SAE form. **Please do not place any SAE information on this Fax Cover Sheet.**

Protocol:	B1931022
Center ID:	1262
Patient #:	
Pfizer AER #: (if available)	

Please fax the SAE Form to 866-997-8322 as soon as possible.

If you have any questions, please call (800) 752-9737.

THANK YOU for your immediate attention to this matter.

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To: Pfizer U.S. Clinical Trial, Drug Safety and Surveillance	
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Center Contact Phone:	**Center Contact Fax:**

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Protocol:	**B0151003**
Center ID:	1262
Patient #:	
Pfizer AER #: (if available)	

Please fax the SAE Form to 866-997-8322 as soon as possible.

If you have any questions, please call (800) 752-9737.

THANK YOU for your immediate attention to this matter.

Serious Adverse Event Report Form

AER # (insert when known)									

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Local #	Date Reported to Pfizer
	- -

PROTOCOL # B1931022 **SUBJECT #** 1 2 6 2

Protocol Title: An Open-label, Randomized Phase 3 Study of Inotuzumab Ozogamicin Compared to a Defined Investigator's Choice in Adult Patients with Relapsed or Refractory CD22-Positive Acute Lymphoblastic Leukemia (ALL)

☐ **Initial Report** ☐ **Follow-Up Report** Data Entry Mode: Electronic **Country where event occurred:**

Patient Data ☐ Male ☐ Female Date of Birth - - (DD-MMM-YYYY) Weight ☐ lb ☐ kg Height ☐ in ☐ cm

Ethnicity: ☐ Asian ☐ Black ☐ Hispanic ☐ Native American ☐ White ☐ Other, specify ☒ Cannot ask per local regulations

If patient has died: Date of Death - - (DD-MMM-YYYY) Cause of Death: ☐ Disease Progression ☐ Other, specify:

Was autopsy performed? ☐ Yes ☐ No ☐ Unknown If yes, what was the autopsy determined cause of death:

Patient's Past Medical History
☐ None
☐ Unknown

Provide relevant past medical history below. Include all other illnesses present at time of event. End of event(s) is date of death if due to event, date of recovery or recovery with sequelae (of last event if multiple events), or date patient's condition stabilized.
If more space is needed, use supplemental page, and check this box: ☐

Illness	Onset Date DD-MMM-YYYY	Stop Date DD-MMM-YYYY *If no Stop Date, check box if ongoing at time of last observation during or at end of event(s)*	Pertinent Details *Include surgical procedures and dates*
	- -	- - ☐	
	- -	- - ☐	
	- -	- - ☐	
	- -	- - ☐	
	- -	- - ☐	
	- -	- - ☐	
	- -	- - ☐	
	- -	- - ☐	

Relevant Tests
☐ None
☐ Unknown

List only relevant diagnostic and confirmatory test results for event(s), for example, from blood tests, diagnostic imaging
If more space is needed, use supplemental page, and check this box: ☐

Test	Date DD-MMM-YYYY	Result	Units	Normal Range Low	Normal Range High	Comments
	- -					
	- -					
	- -					
	- -					
	- -					
	- -					
	- -					

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Study Drug Generic name Trade name Formulation	Indication	Route	Most recent dose before the event	Regimen	Start Date (Overall) DD-MMM-YYYY	Stop Date DD-MMM-YYYY *If no Stop Date, check box if still ongoing at time of last observation during or at the end of event(s)*	Last Action Taken during Event(s) ***Check one only***
inotuzumab ozogamicin *powder for solution for infusion*	*Acute Lymphoblastic Leukemia (ALL)*	*IV*	*mg*	*weekly, 3-4 week Cycle*	- -	- - ☐	☐ Withdrawn permanently ☐ Withdrawn temporarily or delayed ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
FLAG: fludarabine *tradename* *formulation*	*Acute Lymphoblastic Leukemia (ALL)*	*IV*	*mg*	*days 2-6, 4 week cycle*	- -	- - ☐	☐ Withdrawn permanently ☐ Withdrawn temporarily or delayed ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
FLAG: cytarabine *tradename* *formulation*	*Acute Lymphoblastic Leukemia (ALL)*	*IV*	*g*	*days 1-6, 4 week cycle*	- -	- - ☐	☐ Withdrawn permanently ☐ Withdrawn temporarily or delayed ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
FLAG: filgrastim *tradename* *formulation*	*(please specify)*	☐ *IV* *or* ☐ *subcutaenous*	*ug*	*Please specify regimen*	- -	- - ☐	☐ Withdrawn permanently ☐ Withdrawn temporarily or delayed ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
cytarabine+mitoxantrone: Cytarabine *tradename* *formulation*	*Acute Lymphoblastic Leukemia (ALL)*	*IV*	*mg*	*days 1-7 continuous infusion, 15-20 day cycle*	- -	- - ☐	☐ Withdrawn permanently ☐ Withdrawn temporarily or delayed ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
cytarabine+mitoxantrone: Mitoxantrone *tradename* *formulation*	*Acute Lymphoblastic Leukemia (ALL)*	*IV*	*mg*	*days 1-3, 15-20 day cycle*	- -	- - ☐	☐ Withdrawn permanently ☐ Withdrawn temporarily or delayed ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
HIDAC: cytarabine *tradename* *formulation*	*Acute Lymphoblastic Leukemia (ALL)*	*IV*	*g*	*every 12 hours; specify the number of doses given during the most recent cycle*	- -	- - ☐	☐ Withdrawn permanently ☐ Withdrawan temporarily or delayed ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable

n/a					- -	- - ☐	☐ Withdrawn permanently ☐ Withdrawn temporarily or delayed ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable
n/a					- -	- - ☐	☐ Withdrawn permanently ☐ Withdrawn temporarily or delayed ☐ Dose reduced ☐ Dose increased ☐ Dose not changed ☐ Unknown ☐ Not applicable

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Concomitant Drugs
☐ None
☐ Unknown

Include all concomitant drugs taken in the two weeks before event onset. Do not include drugs only taken more than two weeks before the event, used to treat the event, or taken only after event onset. Route, dose, units and frequency are needed only for suspect concomitants*. If more space is needed, use additional copies of this page ☐

Drug Name (Trade and Generic) and formulation	Indication	Route*	Most Recent Dose *	Units*	Frequency*	Start Date DD-MMM-YYYY	Stop Date DD-MMM-YYYY *If no Stop Date, check box if ongoing at time of last observation during or at end of event(s)*
						- -	- - ☐
						- -	- - ☐
						- -	- - ☐
						- -	- - ☐
						- -	- - ☐
						- -	- - ☐
						- -	- - ☐
						- -	- - ☐
						- -	- - ☐

Serious Adverse Event Report Form

AER # *(insert when known)*

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SERIOUS ADVERSE EVENT(S)

Specify diagnosis if known, rather than symptoms or signs.

If more than one SAE, use additional copies of this page and check this box ☐.

Serious Adverse Event _____

Onset Date - -
DD-MMM-YYYY

Seriousness Criteria
(check all that apply)

- ☐ Resulted in death
- ☐ Life-threatening
- ☐ Hospitalization/Prolongation of hospitalization
- ☐ Persistent/Significant disability/incapacity
- ☐ Congenital anomaly/Birth defect
- ☐ Important medical event

Status at the time of last observation or at death
(check one)

- ☐ Recovered
- ☐ Recovered with sequelae
- ☐ Recovering
- ☐ Not Recovered
- ☐ Unknown

Date of Recovery: - -
DD-MMM-YYYY

Is there a reasonable possibility that the event is related to *[an answer must be given for each drug below]*:

inotuzumab ozogamicin?	☐ **Yes**	☐ **No**
FLAG: fludarabine?	☐ **Yes**	☐ **No**
FLAG: cytarabine?	☐ **Yes**	☐ **No**
FLAG: filgrastim?	☐ **Yes**	☐ **No**
cytarabine+mitoxantrone: Cytarabine?	☐ **Yes**	☐ **No**
cytarabine+mitoxantrone: Mitoxantrone?	☐ **Yes**	☐ **No**
HIDAC: cytarabine?	☐ **Yes**	☐ **No**
N/A	☐ **Yes**	☐ **No**
N/A	☐ **Yes**	☐ **No**

Is there a reasonable possibility that the event is related to a Concomitant Drug? ☐ **Yes** ☐ **No**

If Yes, specify: _____

Is there a reasonable possibility that the event is related to a Clinical Trial <u>Procedure</u>? ☐ **Yes** ☐ **No**

If Yes, specify: _____

Was Study Drug/Suspect Concomitant readministered after it was stopped?

inotuzumab ozogamicin?	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**
FLAG: fludarabine?	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**
FLAG: cytarabine?	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**
FLAG: filgrastim?	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**
cytarabine+mitoxantrone: Cytarabine?	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**
cytarabine+mitoxantrone: Mitoxantrone?	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**
HIDAC: cytarabine?	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**
N/A	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**
N/A	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**
Suspect Concomitant? Specify:	☐ **Yes**	☐ **No**	☐ **Unknown or not applicable**

If yes, did this event recur? ☐ **Yes** ☐ **No** ☐ **Unknown**

Last Action Taken during Event with Suspect Concomitant, specify
Complete only if there is a suspect concomitant
Check one only

- ☐ **Withdrawn permanently**
- ☐ **Withdrawn temporarily or delayed**
- ☐ **Dose reduced**
- ☐ **Dose increased**
- ☐ **Dose not changed**
- ☐ **Unknown**
- ☐ **Not applicable**

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AER # (*insert when known*)									

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Narrative ***Provide any information regarding the circumstances, sequence, diagnosis and treatment of the event(s) not otherwise reported on this form. Include details of previous treatments with the study drugs. Complete once only for each report; do not repeat for each event. If more space is needed, use additional copies of this page and check this box***
If additional space is needed, use supplemental page, and check this box: ☐

Please select the appropriate regimen:

☐ inotuzumab ozogamicin or ☐ FLAG (fludarabine, cytarabine, filgrastim) or ☐ cytarabine + mitoxantrone or ☐ HIDAC (high dose cytarabine); Please provide details of any deviation in study therapy (in respect to the protocol specified therapy).

Reporter Comments:

Reporter: _____ _____ - -
First Name Last Name *Please* PRINT Date: DD-MMM-YYYY

Address: _____ /
Street City / State Zip Code Country

Telephone: Fax: Email:

Investigator's Name: M Bellido **Investigator (or Designee) SAE Awareness Date:** - -
DD-MMM-YYYY

Investigator or Designee Signature : _____