Serious Adverse Event Form

PLEASE FAX TO +34 914 561 126 WITHIN 24 HOURS

Protocol Code: GEM2012MENOS65 **Patient Number: _____** **Site: _____**

Investigator Information		Patient Information	
Date of Report: ____/____/____ Day Month Year	Report type: ☐ Initial ☐ Follow-up ☐ Final	Date of birth: ____/____/____ Day Month Year	Race: ☐ Caucasian ☐ Black ☐ Asian ☐ Other
Date of Initial Report: ____/____/____ Day Month Year Date the investigator staff became aware of: ____/____/____ Day Month Year		Gender: ☐ Male ☐ Female Medication (Randomisation) No:	
Principal Investigator´s Name:	Tel.( ) _____		
Principal Investigator´s Address:	Fax ( ) _____ Email: _____	Height: ____ cm / or ____ in Weight: ____ Kg / or ____ in	

Study Drug Information (_____)						
Indication for use:	Indication diagnosis date: ____/____/____ Day Month Year			Regimen:		
Study drug name 1: **VELCADE**	First dose: ____/____/____ Day Month Year	Last dose prior to event: ____/____/____ Day Month Year	and Cycle ___, Day ___ (Oncology only)	Dose (in mg):	Route:	Lot:
Study drug name 2: **LENALIDOMIDE**	First dose: ____/____/____ Day Month Year	Last dose prior to event: ____/____/____ Day Month Year	and Cycle ___, Day ___ (Oncology only)	Dose (in mg):	Route:	Lot:
Study drug name 3: **DEXAMETHASONE**	First dose: ____/____/____ Day Month Year	Last dose prior to event: ____/____/____ Day Month Year	and Cycle ___, Day ___ (Oncology only)	Dose (in mg):	Route:	Lot:
Study drug name 4: **MELPHALAN**	First dose: ____/____/____ Day Month Year	Last dose prior to event: ____/____/____ Day Month Year	and Cycle ___, Day ___ (Oncology only)	Dose (in mg):	Route:	Lot:
Study drug name 5: **BUSULFAN**	First dose: ____/____/____ Day Month Year	Last dose prior to event: ____/____/____ Day Month Year	and Cycle ___, Day ___ (Oncology only)	Dose (in mg):	Route:	Lot:

Please attach copies of the following completed CRF pages (if you consider it relevant)

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

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

Test	Date Day Month Year	Value/Units	Results
	____/____/____		
	____/____/____		
	____/____/____		
	____/____/____		

Study contact completing form _____ _____ Principal Investigator _____ _____
Initials Date Initials Date

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Action taken with study drug 1: VELCADE (check all that apply)

☐ Dose continued unchanged

☐ Dose/regimen reduced Date decreased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen increased Date increased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen temporally held Date held: ____/____/____ (Day Month Year)

☐ Discontinued permanently due to this Adverse Event Date of discontinuation: ____/____/____ (Day Month Year)

☐ Patient no longer receive study drug (explain the reason in narrative) Date of last dose: ____/____/____ (Day Month Year)

☐ Not applicable

Relationship:
☐ Non related
☐ Unlikely
☐ Possible
☐ Probable
☐ Definite

Assessment – The SAE is probably associated with:

☐ Another drug/combination therapy drug. Please specify _____

☐ Another condition (e.g. condition under study, intercurrent illness). Please specify _____

☐ Protocol design or procedures (but not to study drug). Please specify _____

Action taken with study drug 2: LENALIDOMIDE (check all that apply)

☐ Dose continued unchanged

☐ Dose/regimen reduced Date decreased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen increased Date increased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen temporally held Date held: ____/____/____ (Day Month Year)

☐ Discontinued permanently due to this Adverse Event Date of discontinuation: ____/____/____ (Day Month Year)

☐ Patient no longer receive study drug (explain the reason in narrative) Date of last dose: ____/____/____ (Day Month Year)

☐ Not applicable

Relationship:
☐ Non related
☐ Unlikely
☐ Possible
☐ Probable
☐ Definite

Assessment – The SAE is probably associated with:

☐ Another drug/combination therapy drug. Please specify _____

☐ Another condition (e.g. condition under study, intercurrent illness). Please specify _____

☐ Protocol design or procedures (but not to study drug). Please specify _____

Action taken with study drug 3: DEXAMETHASONE (check all that apply)

☐ Dose continued unchanged

☐ Dose/regimen reduced Date decreased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen increased Date increased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen temporally held Date held: ____/____/____ (Day Month Year)

☐ Discontinued permanently due to this Adverse Event Date of discontinuation: ____/____/____ (Day Month Year)

☐ Patient no longer receive study drug (explain the reason in narrative) Date of last dose: ____/____/____ (Day Month Year)

☐ Not applicable

Relationship:
☐ Non related
☐ Unlikely
☐ Possible
☐ Probable
☐ Definite

Assessment – The SAE is probably associated with:

☐ Another drug/combination therapy drug. Please specify _____

☐ Another condition (e.g. condition under study, intercurrent illness). Please specify _____

☐ Protocol design or procedures (but not to study drug). Please specify _____

Study contact completing form _____ (Initials) _____ (Date) Principal Investigator _____ (Initials) _____ (Date)

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Protocol Code: GEM2012MENOS65 **Patient Number: _____** **Site: _____**

Action taken with study drug 4: MELPHALAN (check all that apply)

☐ Dose continued unchanged

☐ Dose/regimen reduced Date decreased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen increased Date increased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen temporally held Date held: ____/____/____ (Day Month Year)

☐ Discontinued permanently due to this Adverse Event Date of discontinuation: ____/____/____ (Day Month Year)

☐ Patient no longer receive study drug (explain the reason in narrative) Date of last dose: ____/____/____ (Day Month Year)

☐ Not applicable

Relationship:
☐ Non related
☐ Unlikely
☐ Possible
☐ Probable
☐ Definite

Assessment – The SAE is probably associated with:

☐ Another drug/combination therapy drug. Please specify _____

☐ Another condition (e.g. condition under study, intercurrent illness). Please specify _____

☐ Protocol design or procedures (but not to study drug). Please specify _____

Action taken with study drug 5: BUSULFAN (check all that apply)

☐ Dose continued unchanged

☐ Dose/regimen reduced Date decreased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen increased Date increased: ____/____/____ (Day Month Year) New Dose: _____

☐ Dose/regimen temporally held Date held: ____/____/____ (Day Month Year)

☐ Discontinued permanently due to this Adverse Event Date of discontinuation: ____/____/____ (Day Month Year)

☐ Patient no longer receive study drug (explain the reason in narrative) Date of last dose: ____/____/____ (Day Month Year)

☐ Not applicable

Relationship:
☐ Non related
☐ Unlikely
☐ Possible
☐ Probable
☐ Definite

Assessment – The SAE is probably associated with:

☐ Another drug/combination therapy drug. Please specify _____

☐ Another condition (e.g. condition under study, intercurrent illness). Please specify _____

☐ Protocol design or procedures (but not to study drug). Please specify _____

Adverse Event Information

ADVERSE EVENT (Diagnostic term): _____

AE onset date: ____/____/____ (Day Month Year)

AE became serious: ____/____/____ (Day Month Year)

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/Mild
☐ Grade 2/Moderate
☐ Grade 3/Severe
☐ Grade 4/Life-threatening

Did AE (s) abate after stopping study drug?
☐ NO ☐ YES ☐ NA

Did AE (s) reappear after reintroducing study drug?
☐ NO ☐ YES ☐ NA

Serious Adverse Event Form

Description of Adverse Event(s)

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

Status of SAE at time of this report

- □ Fatal
- □ Completely resolved: ___/___/_____ DD MM YYYY
- □ Not completely resolved
  - □ ongoing and unchanged
  - □ ongoing with increased intensity
  - □ ongoing with decreased intensity

Death Information

Date of death: ___/___/_____ DD MM YYYY

Autopsy performed?
□ Yes □ No

Autopsy report attached?
□ Yes □ No

Death certificate attached?
□ Yes □ No

Cause of death per (specify):

- □ Autopsy Report _____
- □ Death Certificate _____
- □ Other _____

_____	_____	_____
Study contact completing form printed name	Study contact completing form signature	Date
_____	_____	_____
Principal investigator printed name	Principal investigator signature	Date