EMN12/HO129 PCL

SERIOUS ADVERSE EVENT REPORT

Use this form to report all Serious Adverse Events as described in the trial protocol. An **initial report** must be sent to the EMN Data Center within **24 hours**. Complete information in a first **follow up report** must be reported within **2 days**. The final report is to be sent as soon as outcome of SAE is known. For follow up and final reports you may update the existing initial report.

Fax all 3 pages of the report to: EMN Data Center, fax +390116334187, e-mail pharmacovigilance@torinotrial.it

Patient information

EMN Data Center staff only

Patient study number |__|__|__|__|

Sex |__| 1= male 2= female

Date of birth [dd/mm/yyyy] |____||____||_____|

Report information

Site name .....

Investigator *5* .....

Type of report *7* ☐ Initial report ☐ Follow up report ☐ Final report

Date of initial report [dd/mm/yyyy] *8* |____||____||_____|

Date of follow up report [dd/mm/yyyy] *9* |____||____||____| |____||____||____| |____||____||____|

Date of final report [dd/mm/yyyy] *11* |____||____||_____|

Serious Adverse Event information

Adverse Event Term *12*

(**if the event is an SPM, please remember to compile specific report for SPM**)

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Diagnosis of Adverse Event in a single term; if no diagnosis is available yet, please provide the most relevant sign or symptom

Date onset AE [dd/mm/yyyy] *13* |____||____||_____|

Date AE became Serious [dd/mm/yyyy] *14* |____||____||_____|

Reason AE is Serious *15* |__| 1= death 2= life-threatening 3= (prolongation of) hospitalization 4= significant / persistent disability 5= congenital anomaly / birth defect 6= other medically important condition

Severity of AE [CTCAE grade] *46* |__|

Highest grade observed

16 **SAE description and comments** - describe the course of events, include dates and results of tests / procedures / actions taken (for final report: outcome of adverse event, test result etc.)

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Date of report |___||___||_____|

☐ Initial report ☐ Follow up report ☐ Final report Follow

Trial Medication

Patient group 17 |__| 1= Younger patients (18-65 years) 2= Elderly patients (≥ 66years)

Protocol phase during / after which the SAE occurred 18 |__| 1= Before start protocol treatment 2= Induction 3= Intensification 4= autoSCT 5= Consolidation 6= RIC Allo-SCT 7=Maintenance

Carfilzomib and Lenalidomide

Please specify details of the treatment with Carfilzomib and Lenalidomide that the patient has received (if not given during this protocol phase, please report last time received)

19 **Trial medication[1]**	*20* **Total daily dose** (please add units)	*22* **Date first dose** (during this protocol phase)	*23* **Date last dose** (Date last dose prior to SAE)	*24* **Relationship to SAE[2]**	*25* **Action taken as a result of this SAE[3]**
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|

Other trial medication

Please specify details of the other trial medication that the patient received in this protocol phase:

19 **Trial medication[1]**	*20* **Total daily dose** (please add units)	*22* **Date first dose** (during this protocol phase)	*23* **Date last dose** (Date last dose prior to SAE)	*24* **Relationship to SAE[2]**	*25* **Action taken as a result of this SAE[3]**
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|
|__| ……..	|___||___||_____|	|___||___||_____|	|__|	|__|

[1] Trial medication	[2] Relationship to SAE	[3] Action taken
1= Carfilzomib 2= Lenalidomide 3= Dexamethasone 4= Cyclophosphamide 4= G-CSF 4= Melphalan 4= Busulfan 4= Fludarabin	0= unrelated 1= unlikely 2= possible 3= probable 4= definite	0= none, dose not change 1= next dose reduced 2= drug withdrawn (temporarily or permanently) 3= not applicable

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Date of report |____||____||_____|

☐ Initial report ☐ Follow up report ☐ Final report

34 Possible Causes of SAE other than IMP(s) and other Trial medication(s)

please specify if there are circumstances other than trial medication that may have contributed to the SAE or could help explain the SAE

Disease under study (including progression)	47	|__|	0= No 1= Yes
Disease under study could help explain the SAE or may have caused the SAE			
Medical condition(s)	48	|__|	0= No 1= Yes, specify below
Any relevant past or current medical disorders (not disease under study), allergies, surgeries that could help explain the SAE			
Concomitant medication(s)	49	|__|	0= No 1= Yes, specify below
Any relevant concomitant medication(s) that could help explain the SAE or may have caused the SAE			
Trial related procedure(s) (*e.g. placing IV line or bone marrow biopsy)*	50	|__|	0= No 1= Yes, specify below
Other	51	|__|	0= No 1= Yes, specify below

Specification:……..

……..

……..

……..

Outcome of SAE

Outcome of SAE 35 |__|

1= resolved*
2= ongoing
3= death *(caused by SAE)***
4= ongoing at death *(death due to another cause)***
5= ongoing closed *(because stable situation reached)*

* Date SAE resolved [dd/mm/yyyy] 36 |____||____||_____|

*** Date of death [dd/mm/yyyy] 38 |____||____||_____|

*** Cause of death 39 ……

Signatures – the (sub) investigator should always review and sign at least the final report

Report	Name reporter	Function	Date	Signature
Initial	……..	……..	|____||____||_____|	……..
Follow up	……..	……..	|____||____||_____|	……..
Follow up	……..	……..	|____||____||_____|	……..
Follow up	……..	……..	|____||____||_____|	……..
Final	……..	**(sub) investigator**	|____||____||_____|	……..

EMN Data Center staff only

SAE sequence number 2 |__|__|

Initial report reviewed by (initials) …….. Date review |____||____||_____|

Follow up report reviewed by (initials) …….. Date review |____||____||_____|

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Final report reviewed by (initials) ……..... Date review |___||___||_____|