# HOVON 89 MDS



## 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 HOVON 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: HOVON Data Center, fax +31 (0)10 42 39 084**

### Patient information

*HOVON 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*

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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Pat. Study number: |__|__|__|__| Date of report |___||___||_____|

☐ Initial report ☐ Follow up report ☐ Final report

## Trial Medication

Treatment arm (for randomized trial) *17* |__| 1= arm A (Lenalidomide monotherapy) 2=arm B (Lenalidomide and Epo/G-CSF)

Protocol phase during / after which the SAE occurred *18* |__| 0= before start protocol treatment 1= cycle 1 2= cycle 2 3= cycle 3….. 12= cycle 12 13= maintenance cycle 1 14= maintenance cycle 2 etc 88= Follow up

## IMP(s)

***Please specify details of the Lenalidomide, Epo, G-CSF treatment 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] |
|---|---|---|---|---|---|
| |__| …….. | |___||___||_____| | |___||___||_____| | |__| | |__| |
| |__| …….. | |___||___||_____| | |___||___||_____| | |__| | |__| |
| |__| …….. | |___||___||_____| | |___||___||_____| | |__| | |__| |

| [1] Trial medication | [2] Relationship to SAE | [3] Action taken |
|---|---|---|
| 1= Lenalidomide<br>2= Epo<br>n= G-CSF | 0= unrelated<br>1= unlikely<br>2= possible<br>3= probable<br>4= definite | 0= none<br>1= next dose reduced<br>7 = drug withdrawn (temporarily or permanently)<br>6= not applicable |

## *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. bone marrow biopsy)* *50* |__| 0= No 1= Yes, specify below

Other *51* |__| 0= No 1= Yes, specify below

Specification:……

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## Outcome of SAE

**Outcome of SAE** *35* |__|

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

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

** Date of death [dd/mm/yyyy] *39* |___||___||_____|

** Cause of death *40* ……

## 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** | |___||___||_____| | …… |

## HOVON Data Center staff only

**SAE sequence number** *2* |__|__|

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

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

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