(S)AE instructie HOVON 109

Local Investigator:	Drs. M. Nijland	
Onderzoeksverpleegkundige:	Henriette Klooster	tel: **49265**
Datamanager:	IKNL	tel: **12177**

- 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 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: 010 423 90 13
TEL: 010 70 41 560

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

HOVON 109 CLL

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 4239013

Patient information

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

Sex |__| 1= male 2= female

Weight [kg] 3 |__|__|__|

Date of birth [dd/mm/yyyy] |___||___||_______|

Height [cm] 4 |__|__|__|

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

A serious adverse event that also qualifies as a Dose Limiting Toxicity or as an event to be reported on a Rapid Reporting Form should ALSO be reported on the appropriate forms within 24 hours.

Adverse Event Term* 12

Diagnosis of Adverse Event in a single term; ....

preferably use the CTCAE term — if no diagnosis is available yet, please provide the most relevant sign or symptom

***Hematologic toxicity, Tumor Lysis Syndrome and Tumor Flare Reaction should be scored according to protocol appendix H, protocol appendix I cq protocol appendix J**

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

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Pat. Study number: |__|__|__|__|__| Date of report |__||__||____|

☐ Initial report ☐ Follow up report ☐ Final report

Trial Medication

Phase of the trial 17 |__| 1= phase I 2=phase 2

Protocol phase during / after which the SAE occurred 18 |__|__| 0= before start protocol treatment [1-12]= during cycle [I-XII]

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

19 Trial medication[1]	20 Dose (units)	21 Route (iv, po,..)	22 Date first dose (during this protocol phase)	23 Date last dose (prior to SAE)	24 Relationship to SAE[2]	25 Action taken[3]	26 If discontinued: Did Event abate?[4]	27 If restarted: Did Event reappear?[4]
|__|	....	....	|__||__||____|	|__||__||____|	|__|	|__|	|__|	|__|
|__|	....	....	|__||__||____|	|__||__||____|	|__|	|__|	|__|	|__|
|__|	....	....	|__||__||____|	|__||__||____|	|__|	|__|	|__|	|__|
|__|	....	....	|__||__||____|	|__||__||____|	|__|	|__|	|__|	|__|
|__|	....	....	|__||__||____|	|__||__||____|	|__|	|__|	|__|	|__|
|__|	....	....	|__||__||____|	|__||__||____|	|__|	|__|	|__|	|__|
|__|	....	....	|__||__||____|	|__||__||____|	|__|	|__|	|__|	|__|
|__|	....	....	|__||__||____|	|__||__||____|	|__|	|__|	|__|	|__|

[1] Trial medication	[2] Relationship to SAE	[3] Action taken		[4] Abate / reappear
1= Chlorambucil 2= Rituximab 3=Lenalidomide	0= unrelated 1= unlikely 2= possible 3= probable 4= definite	0= none 1= next dose reduced 2= next dose delayed 3= next dose reduced *and* delayed	4= discontinued temporarily 5= discontinued permanently 6= not applicable	0= no 1= yes 2= not applicable

Relevant concomitant medication

– report medication received up to 30 days prior to the date onset AE, limited to relevant prophylaxis and supportive care administered with the aim to prevent an AE such as is now reported and medication that the investigator considers to be possibly contributing to the occurrence of the SAE. Do not report medication given to treat the SAE.

28 Drug (generic name)	29 Dose (units)	30 Route (iv, po,..)	31 Indication	32 Date first dose	33 Date last dose (prior to SAE)
....	....	....	....	|__||__||____|	|__||__||____|
....	....	....	....	|__||__||____|	|__||__||____|
....	....	....	....	|__||__||____|	|__||__||____|
....	....	....	....	|__||__||____|	|__||__||____|
....	....	....	....	|__||__||____|	|__||__||____|
....	....	....	....	|__||__||____|	|__||__||____|
....	....	....	....	|__||__||____|	|__||__||____|

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34 Relevant medical history – please specify if there are circumstances other than trial medication that may have contributed to the SAE

Disease under study including progression	47	|__|	0= No	1= Yes
Concomitant disease or allergy	48	|__|	0= No	1= Yes, specify below
Concomitant medication	49	|__|	0= No	1= Yes, see relevant concomitant medication section
Trial related procedure	50	|__|	0= No	1= Yes, specify below
Other	51	|__|	0= No	1= Yes, specify below

Specification:..

....

....

Additional SAE information

Outcome of SAE 35 |__| 1= resolved completely* 2= resolved with sequelae* 3= ongoing 4= death** 5= ongoing at death**

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

If patient was hospitalized (at any time during the SAE and regardless of causal relationship with SAE)

Date of hospitalization [dd/mm/yyyy] 37 |___||___||______|

Date of discharge [dd/mm/yyyy] 38 |___||___||______|

*****If patient died*** (regardless of causal relationship with SAE)

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

Cause of death 40 ....

Autopsy performed 41 |__| 0= no 1= yes

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 |___||___||______|	Additional info needed?	|__|	0= no	1= yes
Follow up report reviewed by (initials)	....	Date review |___||___||______|	Additional info needed?	|__|	0= no	1= yes
			Re-assessment needed?	|__|	0= no	1= yes
Final report reviewed by (initials)	....	Date review |___||___||______|	Additional info needed?	|__|	0= no	1= yes
			Re-assessment needed?	|__|	0= no	1= yes