ETAL-4 / HOVON-145

Serious Adverse Event Report (SAE)
FAX No.: +49-(0)-69-6301-7463

Patient-ID	Date of this Report	To be completed by Safety Desk: **SAE-No.**	
E _|_|_|-_|_|_|	|_|_|_|_|20|_|_|	**Date of receipt**	

(1) Type of Report

☐ Initial report ☐ Follow-Up report no. |_|_|

(2) Patient Year of birth: |_|_|_|_| Sex: ☐ male ☐ female

(3) Onset of SAE Date: |_|_|_|_|20|_|_|

(4) End of SAE Date: |_|_|_|_|20|_|_| ☐ still ongoing

(5) Status of SAE

☐ Recovered/Resolved ☐ Recovering/Resolving ☐ Unknown
☐ Recovered/Resolved with sequelae ☐ Not recovered/Not resolved ☐ Fatal

(6) SAE-criteria (SAE, please refer to exceptions according to the protocol)

☐ Results in death
☐ Is life-threatening
☐ Requires patient hospitalization or causes prolongation of existing hospitalization
☐ Results in persistent or significant disability/incapacity
☐ Is a congenital anomaly or birth defect
☐ Any other medical event considered serious by the treating physician: *(please, specify)*

_____

☐ Death to any cause
☐ Overdose of the study drug
☐ Misuse or abuse of the study drug
☐ *Pregnancy or fathering by a patient on study drug must be reported on separate pregnancy report form*

If SAE-Criteria "Results in death" was chosen, please fill in:

Date of Death |_|_|_|_|20|_|_| Autopsy? ☐ Yes (please send report) ☐ No

Cause(s) of death:_____

(7) SAE Diagnosis (please refer to AE term according to CTCAE 4.03; in case that more than one AE term/diagnosis is mentioned, underline the main diagnosis. In case of more than one main diagnosis, fill in separate SAE form!)

Maximum severity of main diagnosis (1 - 5) CTCAE V. 4.03: |___|

(8) SAE Description

(signs/symptoms, diagnosis, treatment (if necessary also under no. 19), if applicable, attach relevant findings)

(9) Therapy Arm

Patient was randomized to

☐ Arm A (Panobinostat)

or

☐ Arm B (SOC)

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(10) Administration of Study Drug

☐ Arm A Panobinostat Start date of the current cycle _|_|_|_|20|_|_| ddmmyyyy	Date of last dose given _|_|_|_|20|_|_| ddmmyyyy	Dose given at onset of event _____ (amount, unit, frequency)

☐ Arm B SOC

(11) Relevant Laboratory Parameters / Examination (only if necessary for SAE-diagnosis or -description)

☐ None ☐ Unknown

Laboratory parameters/investigations	Date (dd.mm.yyyy)	Result	Unit	Normal range *from – to*

Comments (if necessary also under no.19)

(12) Relevant Medical History (related to SAE)

☐ None ☐ Unknown

Disease	Date of onset (if known, otherwise "unknown")	Ongoing at the time of SAE?	Date of end (if known, otherwise "unknown")
		☐	
		☐	
		☐	
		☐	
		☐	

(13) <u>For Arm A only</u>: Relationship to Study Drug

Panobinostat ☐ definitely related ☐ probably ☐ possibly ☐ unlikely ☐ unrelated

Concomitant Medication ☐ definitely related ☐ probably ☐ possibly ☐ unlikely ☐ unrelated

_____
(name of medication)
Please specify further details and further relevant concomitant medication under no. 15

(14) <u>For Arm B only</u>: Relationship

Concomitant Medication ☐ definitely related ☐ probably ☐ possibly ☐ unlikely ☐ unrelated

_____
(name of medication)
Please specify further details and further relevant concomitant medication under no. 15

(15) <u>Relevant</u> Concomitant Medication in a possible time-related or causal Relationship with SAE (please record all medication for treatment of SAE under no.18)

☐ No ☐ Unknown

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Active substance name	Duration of therapy		Medication ongoing	Dose (amount, unit, route, frequency)	Reason for application
	Start (dd.mm.yyyy)	**End** (dd.mm.yyyy)			
			☐		
			☐		
			☐		
			☐		
			☐		

(16) For Arm A and Arm B: Other possible Reasons for SAE (e.g. other interventions, pre-existing disease, others)

☐ None

☐ Graft-versus-Host Disease (GvHD)

☐ Immunosuppression

☐ Other transplant-associated complication, please specify:

(17) Last Actions taken in Response to Event regarding Panobinostat

☐ Drug withdrawn ☐ Dose not changed ☐ Dose reduced ☐ Dose interrupted/delayed ☐ Dose increased

☐ Unknown ☐ Not applicable

(18) Therapy of SAE

Medication/non-drug therapy	Duration of therapy		Medication ongoing	Dose (amount, unit, route, frequency)
	Start (dd.mm.yyyy)	End (dd.mm.yyyy)		
			☐	
			☐	
			☐	
			☐	

(19) Additional Information and Comments

(20) Telephone and Fax number of Investigator Telephone: Fax:

(21) Investigator Awareness Date ☐☐☐☐20☐☐ ddmmyyyy

Stamp Date Name of Investigator (block letters) Signature of Investigator

Please send by fax to Safety Desk ETAL-4 / HOVON-145 – Fax-No.: +49 (0) 69 6301 7463