



# HOVON 127 BL

## SERIOUS ADVERSE EVENT REPORT

Mail reports to: HOVON Data Center, saereports@erasmusmc.nl

Pat. Study number: |\_|\_|\_|\_|\_|\_|\_|\_|

Date of report |\_|\_|||\_|\_|||\_|\_|\_|\_|

Initial report

Follow up report

Final report

### Trial Medication

Treatment arm (for randomized trial) 17 |\_|\_| 1= arm A (dmR-CODOX-M and R-IVAC) 2=arm B (DA-EPOCH-R)  
 Protocol phase during / after which the SAE occurred 18 |\_|\_| 0=before start protocol treatment 1=Cycle 1 R-CODOX-M 2=Cycle 1 R-IVAC  
 3= Cycle 2 R-CODOX-M 4=Cycle 2 R-IVAC 5= Cycles 1 to 3 DA-EPOCH-R  
 6= cycles 4 to 6 DA-EPOCH- R 7= Follow Up

### Investigational Medicinal Products (IMP(s))

*Please specify details of the IMP(s) treatment that the patient has received (if not given during this protocol phase, please report last time received)*

19 Trial medication	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 <sup>2</sup>	25 Action taken as a result of this SAE <sup>3</sup>
Cyclophosphamide .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Vincristine .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Doxorubicin .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Cytarabine (i.v.) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Prednisolone (p.o.) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Methotrexate (i.v.) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Ifosfamide .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Etoposide .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Rituximab (i.v.)* .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
*Brand name	_ _  MabThera	_ _  Blitzima	_ _  Rixathon	_ _  Rituzena	
Rituximab	_ _  Truxima	_ _  Ritemvia	_ _  Riximyo		

### Other trial medication

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

19 Trial medication <sup>1</sup>	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 <sup>2</sup>	25 Action taken as a result of this SAE <sup>3</sup>
Cytarabine (i.t) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Leucovorin (i.v) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Filgrastim (s.c.) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Methotrexate (i.t.) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Mesna (i.v) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Dexamethasone (i.t.) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Prednisolone (i.t.) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_
Leucovorin (p.o.) .....	_ _	_ _ _ _ _	_ _ _ _ _	_	_

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	<sup>2</sup> Relationship to SAE	<sup>3</sup> Action taken
	0= unrelated 1= unlikely 2= possible 3= probable 4= definite	0= none 1= next dose reduced 7 = drug withdrawn (temporarily or permanently) 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. placement PICC line or subclavian catheter) 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\*  
 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	.....	<b>(sub) investigator</b>	_ _   _ _   _ _ _ _	.....

