RACE TRIAL
EudraCT №:
2014-000363-40

A prospective Randomized multicentre study comparing horse Antithymocyte globuline (hATG) + Cyclosporine A (CsA) with or without Eltrombopag as front-line therapy for severe aplastic anemia patients

Please fax completed form within 24 hours of notification to:
+31 71 526 6185

SERIOUS ADVERSE EVENT REPORT

CIC: ☐☐☐☐	Patient Trial Number: ☐☐☐	Patient Initials ☐☐☐
EBMT use only:	SAE ID: ☐☐☐☐☐	Received date: *(stamp)* Time: ☐☐:☐☐

Type of Report: ***(check one box only)*** ☐ Initial ☐ Follow-Up

Date of this report ☐☐☐☐☐☐☐☐ (d d m m m y y y y)

Date when PI became aware of the SAE: ☐☐☐☐☐☐☐☐ (d d m m m y y y y)

Site Information

EBMT Centre Identification Code (CIC): ☐☐☐☐	Responsible physician:	
Hospital:	Unit:	
City:	Country:	
E-Mail:	Telephone:	Fax:

Patient Details

Initials: ☐☐☐ *eg. J-S, LMD*

Date of birth: ☐☐☐☐☐☐☐ *(e.g. 01 JAN 07)* (d d m m m y y)

Sex: ☐Male ☐Female

Height: ☐☐☐ cm

Weight: ☐☐.☐ kg

Details of SAE

Adverse Event Term: _____

(use CTCAE Short Name of adverse event http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_5x7.pdf

Onset date: ☐☐☐☐☐☐☐ (d d m m m y y)

Severity: ☐

(use CTCAE Grading Scale http://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_5x7.pdf

Why was the event serious?

- ☐ Fatal
- ☐ Life-threatening
- ☐ New/prolonged inpatient hospitalisation
- ☐ Persistent or significant disability/incapacity
- ☐ Congenital anomaly/birth defect
- ☐ Other significant medical event

Outcome at the time of the report:

- ☐ Recovered/Resolved, date: ☐☐☐☐☐☐☐ (d d m m m y y)
- ☐ Recovered/Resolved with sequelae ***(please provide follow-up report)***
- ☐ Recovering/Resolving
- ☐ Not recovered/Not resolved
- ☐ Unknown
- ☐ Fatal, date: ☐☐☐☐☐☐☐ (d d m m m y y)

cause of death:.....

autopsy report available: ☐ No ☐ Yes

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Protocol Treatment

Trial arm: *(tick one box only)* ☐ arm A (hATG + CsA) ☐ arm B (hATG + CsA + Eltrombopag)

Date of last trial drug given prior to SAE: ☐☐☐☐☐☐☐☐ (d d m m m y y)

Was the trial treatment given at full protocol dose prior to event? ☐ No *(specify):*..... ☐ Yes

Trial Drug 1	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
	Eltrombopag olamine	**Revolade**				

Start Date: ☐☐☐☐☐☐☐☐ (d d m m m y y) **Stop Date:** ☐☐☐☐☐☐☐☐ (d d m m m y y) **Continuing:** ☐ No ☐ Yes

Causal Relationship of Eltrombopag olamine to Event:	**Action Taken:**	**Reaction Subsided after Stopping Drug:**	**Reaction Reappeared after Reintroduction:**
☐ Related ☐ Not Related	☐ None ☐ Dose reduction ☐ Treatment delayed ☐ Treatment delayed & reduced ☐ Treatment permanently stopped	☐ No ☐ Yes ☐ NA	☐ No ☐ Yes ☐ NA

Trial Drug 2	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
	Horse ATG	**ATGAM**				

Start Date: ☐☐☐☐☐☐☐☐ (d d m m m y y) **Stop Date:** ☐☐☐☐☐☐☐☐ (d d m m m y y) **Continuing:** ☐ No ☐ Yes

Causal Relationship of hATG to Event:	**Action Taken:**	**Reaction Subsided after Stopping Drug:**	**Reaction Reappeared after Reintroduction:**
☐ Related ☐ Not Related	☐ None ☐ Dose reduction ☐ Treatment delayed ☐ Treatment delayed & reduced ☐ Treatment permanently stopped	☐ No ☐ Yes ☐ NA	☐ No ☐ Yes ☐ NA

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EBMT use only:	SAE ID: ☐☐☐☐☐	Received date: *(stamp)* Time: ☐☐:☐☐

Trial Drug 3	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
	Cyclosporin A					

Start Date: ☐☐☐☐☐☐☐☐ (d d m m m y y)	**Stop Date:** ☐☐☐☐☐☐☐☐ (d d m m m y y)	**Continuing:** ☐ No ☐ Yes

Causal Relationship of CsA to Event:	**Action Taken:**	**Reaction Subsided after Stopping Drug:**	**Reaction Reappeared after Reintroduction:**
☐ Related ☐ Not Related	☐ None ☐ Dose reduction ☐ Treatment delayed ☐ Treatment delayed & reduced ☐ Treatment permanently stopped	☐ No ☐ Yes ☐ NA	☐ No ☐ Yes ☐ NA

Event Description *(include relevant symptoms, body site, treatment received, dates of hospital admission and discharge)*
☐ *(check box if continued on an additional page – please attach)* → Number of additional pages attached: ☐

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EBMT use only:	SAE ID: ☐☐☐☐☐	Received date: *(stamp)* Time: ☐☐:☐☐

Concomitant Medications *(only include drugs given within the last 30 days excluding treatment for SAE)*

	Name	Brand	Indication	Dose	Frequency	Route
Drug 1						
Start Date: ☐☐☐☐☐☐☐ (d d m m m y y)	**Stop Date:** ☐☐☐☐☐☐☐ (d d m m m y y)	**Continuing:** ☐ No ☐ Yes				
Drug 2						
Start Date: ☐☐☐☐☐☐☐ (d d m m m y y)	**Stop Date:** ☐☐☐☐☐☐☐ (d d m m m y y)	**Continuing:** ☐ No ☐ Yes				
Drug 3						
Start Date: ☐☐☐☐☐☐☐ (d d m m m y y)	**Stop Date:** ☐☐☐☐☐☐☐ (d d m m m y y)	**Continuing:** ☐ No ☐ Yes				
Drug 4						
Start Date: ☐☐☐☐☐☐☐ (d d m m m y y)	**Stop Date:** ☐☐☐☐☐☐☐ (d d m m m y y)	**Continuing:** ☐ No ☐ Yes				

☐*(tick box if continued on an additional page – please attach)*→ Number of additional pages attached: ☐

Relevant Laboratory/Diagnostic Tests

Date	Test	Results
☐☐☐☐☐☐☐ (d d m m m y y)		☐Results pending *(check box if applicable)*
☐☐☐☐☐☐☐ (d d m m m y y)		☐Results pending *(check box if applicable)*
☐☐☐☐☐☐☐ (d d m m m y y)		☐Results pending *(check box if applicable)*
☐☐☐☐☐☐☐ (d d m m m y y)		☐Results pending *(check box if applicable)*
☐☐☐☐☐☐☐ (d d m m m y y)		☐Results pending *(check box if applicable)*

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EBMT use only:	SAE ID: ☐☐☐☐☐	Received date: *(stamp)*	Time: ☐☐:☐☐

Relevant Medical History & Additional Comments

Was this event expected in view of the patient's clinical history? ☐No ☐Yes

Form(s) Completed By:

Print name: ..... Signature: ..... Date: ☐☐☐☐☐☐☐☐ (d d m m m y y)

Investigator Authorisation:

Print name: ..... Signature: ..... Date: ☐☐☐☐☐☐☐☐ (d d m m m y y)

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EBMT use only:	SAE ID: ☐☐☐☐☐	Received date: *(stamp)*	Time: ☐☐:☐☐

To be Completed by EBMT Clinical Trials Office Only:

SAE EVALUATION ***(If follow up SAE check the initial report)***

Drug/Intervention:	**Eltrombopag Olamine**	**hATG, ATGAM**	**Cyclosporin A**
Expectedness*:	☐ Unexpected ☐ Expected	☐ Unexpected ☐ Expected	☐ Unexpected ☐ Expected

SAE Classification: ☐ SAE ☐ SSAR ☐ SUSAR

Assessed by *(print name)*:.....Signature:.....

Date assessed: ☐☐☐☐☐☐☐☐
d d m m m y y

***** Event expected for this drug: please, consult the Investigator's Brochure or SMPC for already reported side effects of this drug. Expectedness evaluating the event in relationship to the drug and not to the patient

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EBMT use only:	SAE ID: ☐☐☐☐☐	Received date: *(stamp)*	Time: ☐☐:☐☐

Concomitant Medications (continued) *(only include drugs given within the last 30 days excluding treatment for SAE)*

Drug	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
Start Date: ☐☐☐☐☐☐☐ d d m m m y y		**Stop Date:** ☐☐☐☐☐☐☐ d d m m m y y		**Continuing:** ☐ No ☐ Yes		

Drug	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
Start Date: ☐☐☐☐☐☐☐ d d m m m y y		**Stop Date:** ☐☐☐☐☐☐☐ d d m m m y y		**Continuing:** ☐ No ☐ Yes		

Drug	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
Start Date: ☐☐☐☐☐☐☐ d d m m m y y		**Stop Date:** ☐☐☐☐☐☐☐ d d m m m y y		**Continuing:** ☐ No ☐ Yes		

Drug	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
Start Date: ☐☐☐☐☐☐☐ d d m m m y y		**Stop Date:** ☐☐☐☐☐☐☐ d d m m m y y		**Continuing:** ☐ No ☐ Yes		

Drug	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
Start Date: ☐☐☐☐☐☐☐ d d m m m y y		**Stop Date:** ☐☐☐☐☐☐☐ d d m m m y y		**Continuing:** ☐ No ☐ Yes		

Drug	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
Start Date: ☐☐☐☐☐☐☐ d d m m m y y		**Stop Date:** ☐☐☐☐☐☐☐ d d m m m y y		**Continuing:** ☐ No ☐ Yes		

Drug	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**
Start Date: ☐☐☐☐☐☐☐ d d m m m y y		**Stop Date:** ☐☐☐☐☐☐☐ d d m m m y y		**Continuing:** ☐ No ☐ Yes		

Drug	*Name*	**Brand**	**Indication**	**Dose**	**Frequency**	**Route**

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Start Date: ☐☐☐☐☐☐☐☐ d d m m m y y	**Stop Date:** ☐☐☐☐☐☐☐☐ d d m m m y y	**Continuing:** ☐ No ☐ Yes

ADDITIONAL PAGE – USE IF REQUIRED

Details of SAE (continued)

Event Description continued*(include relevant symptoms, body site, treatment received, dates of hospital admission and discharge)*