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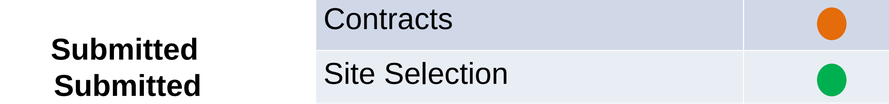
EBMT
European Society for Blood and Marrow Transplantation

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

Supported by GlaxoSmithKline and Pfizer

Working party	Principal investigators	Trial Coordinator
SAA-WP	**Antonio M Risitano / Regis Peffault de Latour**	**Astrid Hoeppener**
	To investigate whether **Eltrombopag** (Revolade, GSK) added to standard immune-suppressive treatment, CsA + hATG (ATGAM, Pfizer) increases the rate of early complete response in untreated AA patients* * Patients will be stratified by age and disease severity	
Participating countries		

Main Inclusion criteria:

1) Diagnosis of severe or very severe aplastic anemia, defined by:
   - At least two of the following:
     - ✓ Absolute neutrophil counts <0,5 x 10^9/L (severe) or <0,2 x 10^9/L (very severe)
     - ✓ Platelets counts <20 x 10^9/L
     - ✓ Reticulocyte counts <60 x 10^9/L
   - Hypocellular bone marrow (<30% cellularity without evidences of fibrosis or malignant cells)
2) Male or female age ≥ 15 years

Primary endpoint:

Rate of complete response (defined as Hb>10 g/dL, ANC>1,000/µL and Plt>100,000 µL) at 3 months since start of treatment in untreated severe AA patients.

Submission Status

France: Submitted
Italy: Submitted
United Kingdom: April 2015
The Netherlands: April 2015
Spain: April 2015
Switzerland: April – May 2015
Germany: April – May 2015

Milestone	Status
Contracts	
Site Selection	
Site Agreements	
Study Drugs	
Submission to EC and CA	
First Subject, First visit	

RACE Study Kick-Off Meeting

RACE update, Protocol reminders, Study drug info, CRF

Centres participating in the RACE trial

15 April 2015, 10am – 4pm

Saint Louis Hospital, Paris

For further information, please visit the Working Party:

Aplastic Anemia oral session

23-March, 13:45-15:15, room: çamlica hall

Or contact the Trial Coordinator:

Astrid Hoeppener, astrid.hoeppener@ebmt.org, +31 (0)71 526 1183

Trial to Evaluate Safety and Efficacy of MK-8228 (Letermovir) for the Prevention of Human Cytomegalovirus (CMV) Viremia and/or Disease in Adult CMV Seropositive Allogeneic HSCT subjects

Sponsor: Merck (MSD)
Supported by the EBMT (providing recruitment and retention service)

Background

CMV remains an important complication after HSCT. Serum seropositivity in recipients is also associated with decreased survival. Current anti-CMV agents are not routinely used and those that are, are associated with significant toxicity, with drug resistance to them increasing. Letermovir is an anti-viral agent with a novel mechanism of action that has been shown to be safe and well tolerated in Phase I and II trials.

Main Aim

To evaluate the efficacy, safety and tolerability of MK-8228 (Letermovir) in the prevention of clinically significant CMV infection post-transplant.

Main inclusion criteria

- Adults only ≥ 18 years of age
- Subjects scheduled for first allogeneic hematopoietic stem cell transplant (HSCT)
- Must have documented CMV seropositivity in last 1 year
- No active CMV viremia
- Randomization must be within 28 days post-transplant

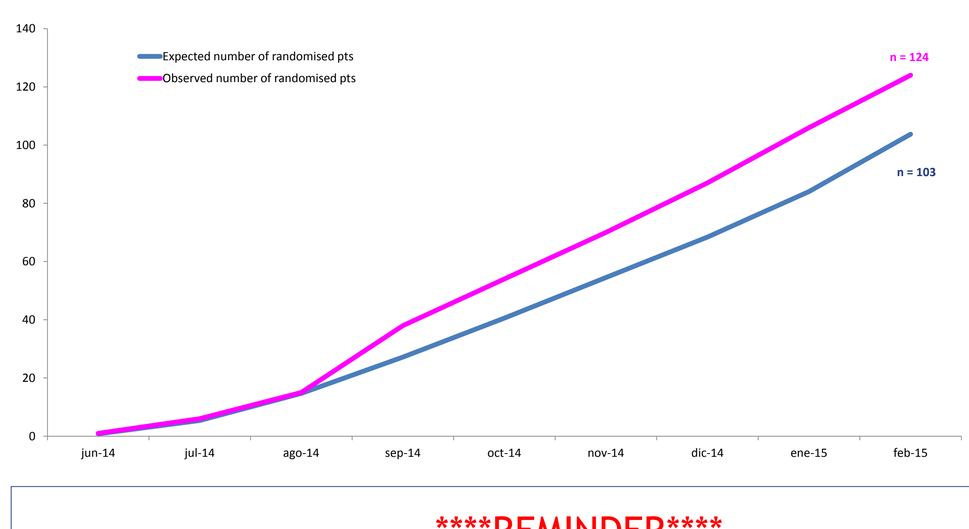
Recruitment period	Recruitment target
June 2014 - June 2016	540 randomised patients

Table 1 Current number of patients randomised (by March 1st 2015) by country (those in red are countries not supported by the EBMT)

Region	Country	Number of sites per country	Total patients randomised to date (% of total patients minimal expected for this country)
Europe	Austria	2	17 (85%)
	Belgium	2	19 (95%)
	Finland	1	5 (50%)
	France	3	7 (23%)
	Germany	4	15 (38%)
	Italy	4	10 (25%)
	Lithuania	1	0
	Poland	2	5 (25%)
	Romania*	2	0
	Spain^	6	9 (15%)
	Sweden	2	12 (60%)
	UK	3	4 (13%)
EEMEA	Turkey	4	9 (23%)
Asia/Pacific	New Zealand	2	2 (10%)
	Japan*	4	0
	South Korea*	3	0
North America	Canada	1	10 (100%)
	US	23	34 (15%)
Latin America	Brazil	3	0
	Peru	1	2 (20%)
Total (EBMT supported)	17 countries	46	124 (23%)
Total (non-EBMT supported)	3 countries	27	34 (13%)
Total (all)	**20 Countries**	**73**	**158 (18%)**

*These countries have not opened to recruitment yet
^Not all sites in these countries are open

Fig 1 Number of patients randomised vs. expected number for EBMT supported sites



****REMINDER****

EBMT Recruitment and Retention Workshop

Monday 23 March 2015 6-7pm, Room: **3B/12 (B3 level)**

All PI's / Sub PI's working on this study are invited. Refreshments provided

This is an ideal opportunity to get updates on protocol amendments, recruitment, and to discuss any recruitment or retention issues. You can also meet some of the EBMT team.

For further information, please email Sue Philpott (EBMT Clinical Trials Coordinator) sue.philpott@ebmt.org