

The primary endpoint is the proportion of patients with at least  $2.0 \times 10^6$  CD34+/kg cells collected.

The trial was designed as a Simon two-stage design. A maximum of 28 donors who were given plerixafor should be assessed for harvest, with an interim analysis after the first 9 donors. In the protocol it is stated:

- If after the first 9 donors  $\leq 6$  (66.7%) successful harvests are observed, the trial will be closed to further donor entry with the conclusion that the regimen is not feasible, and should not be further investigated. Otherwise donor entry will be extended to 28 donors.
- If after 28 donors  $\leq 22$  ( $22/28 = 78.6\%$ , 90% CI = 62.0-90.2%; 90% because  $\alpha = 0.10$ ): successful harvests are observed, the conclusion will be that the regimen is not feasible, and should not be further investigated.
- Otherwise, the trial will conclude that the regimen is feasible, and warrants further investigation in this donor population.

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As of February 20, 2017, in arm A:

- 24 donors have been assigned;
- for 1 donor (PID 31), plerixafor was not given;
- for 1 donor (PID 8) we know (s)he is by definition a failure, because  $1.9 \times 10^6$  CD34+/kg cells after one leucapheresis was considered enough for transplantation. HOWEVER, because of that, a second leucapheresis was not performed. But in patients with a second leucapheresis, the minimum harvest was  $0.9 \times 10^6$  CD34+/kg. Therefore this patient will be considered as a SUCCESS;
- for the other 22 donors we know they are by definition a success, i.e. sufficiently CD34+ cells have been collected.

#### CONCLUSION:

In arm A, there are 23/23 'harvested' donors for whom sufficiently CD34+ cells (would) have been collected. Therefore, in arm A the primary endpoint of the trial has been successfully met.