MaaT033 For Gut Microbiota Optimization To Improve Survival After Allogenic HCT: The PHOEBUS Trial

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Introduction

Allogeneic hematopoietic transplantation (alloHCT) is a well-established therapy for high-risk hematologic malignancies, with nearly 20,000 procedures reported annually to the European Society for Blood and Marrow Transplantation. Despite its effectiveness, outcomes are often limited by relapse, infections, graft-versus-host disease (GvHD) and conditioning-related toxicity. Emerging evidence suggests that gut microbiota diversity plays a critical role in reducing these complications and may even lower relapse risk. Fecal microbiota transplantation offers a promising strategy to restore microbial balance and improve clinical outcomes after alloHCT.

The PHOEBUS trial is a multi-center randomized, double blinded phase IIb trial evaluating the efficacy of MaaT033 in improving survival of adult alloHCT subjects (Clinicaltrials.gov identifier: NCT05762211).

Methods

- Freeze-dried, full-ecosystem, high-richness and diversity, fecal microbiota medicinal product (healthy pooled allogeneic human fecal material), formulated as **delayed-release capsules** .
- MaaT033 has received the **orphan drug designation from the EMA**.

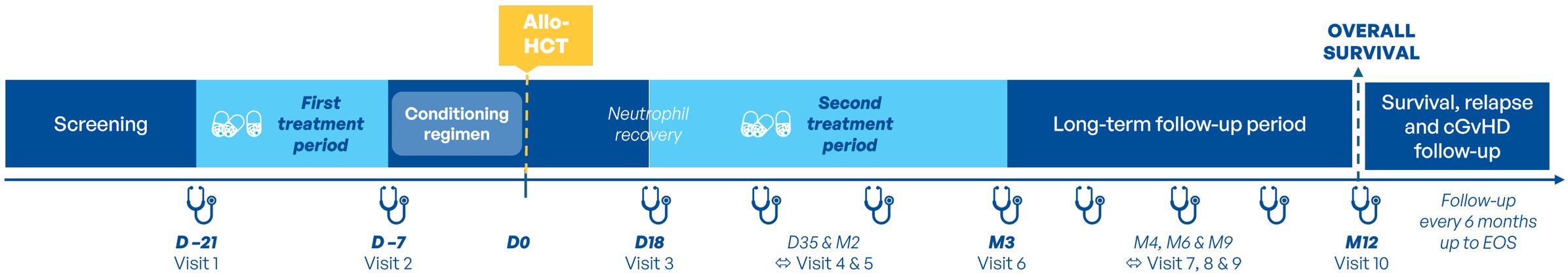
Objectives

1. Primary endpoint: to evaluate OS at 12 months after alloHCT.
2. Secondary endpoints:
   - Evaluation of the safety of MaaT033,
   - GvHD-free survival, GvHD-free/ relapse-free survival at 12 months,
   - Cumulative incidence of acute and chronic GvHD,
   - Non-relapse mortality, incidence of severe infections,
   - Quality of life.

Study Design

PHOEBUS

388 patients treated before and after alloHCT in a randomized, double-blind international trial.



Treatment period (3 caps/day)

Subject visits (including samples, clinical examination...)

Abbreviations:
D: Day; M: Month
Neutrophil recovery is defined as the first day of an absolute neutrophil count > 0.5G/L after alloHCT.

Patient stratification is based on the Disease Risk Index (DRI) and donor-host compatibility (geno- and pheno-identical vs 8/10, 9/10, and haplo-identical).

Main inclusion criteria

- Subjects aged ≥ 50 years
- AlloHCT is indicated with a reduced-toxicity or intensity conditioning regimen.
- Patients with neutrophils > 0.5 G/L
- Patients having received broad-spectrum antibiotics within the last 90 days prior to inclusion

Main exclusion criteria

- Non-myeloablative and conventional myeloablative conditioning regimen
- *In vitro* T-cell depletion
- AlloHCT with cord blood cells
- Use of alemtuzumab, vedolizumab or abatacept for GvHD prophylaxis
- Any history of chronic digestive disease.

For the full list of inclusion and exclusion criteria: Trial No. NCT05762211 - www.ClinicalTrials.gov

Safety Assessments Via DSMBs:

- All safety assessments to date, including the four regular DSMB meetings, have confirmed a favorable safety profile for MaaT033 and have recommended continuation of the trial without modification.
- Two interim safety analyses, conducted after the first 60 and 120 randomized subjects, were favorable, with no safety signals or excess 90-day post-alloHCT mortality attributable to MaaT033.
- Last positive routine DSMB took place in January 2026.

Conclusion

- **Ongoing recruitment**
- **Favorable preliminary safety assessments**

Recruiting countries

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