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MaaT Pharma Reports Phase 3 Data for Microbiome Therapy in Acute GvHD

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The ARES trial data support MaaT013 as a potential third-line treatment for severe gastrointestinal acute graft-versus-host disease.

MaaT Pharma has presented final Phase 3 data from the ARES pivotal trial evaluating MaaT013 in acute graft-versus-host disease with gastrointestinal involvement.

MaaT013 is being developed as a microbiome ecosystem therapy for patients with cancer-related complications. The therapy is currently under review by the European Medicines Agency following a Marketing Authorization Application submitted in June 2025, with a decision expected in mid-2026.

This is relevant because gastrointestinal acute graft-versus-host disease remains a severe complication after hematopoietic stem cell transplantation. Patients who are refractory to corticosteroids and ruxolitinib have limited treatment options and poor outcomes.

The ARES study was a single-arm, open-label trial evaluating MaaT013 as a third-line treatment in 66 adult patients with severe GI-aGvHD across 50 sites in six European countries. At Day 28, gastrointestinal overall response rate reached 62 per cent, with responses maintained at 47 per cent at Day 56 and 44 per cent at Month 3. Overall survival at 12 months was 54 per cent.

The data provide a clinically relevant signal in a difficult-to-treat patient population, although interpretation will need to consider the single-arm study design and the complexity of treating late-line acute GvHD. Regulatory review will be important in determining whether the evidence package is sufficient for market authorization.

MaaT013 also reflects growing interest in microbiome-based therapeutics beyond gastrointestinal disease, particularly in oncology and transplant-related complications. Adoption will depend on regulatory outcome, manufacturing scalability, hospital integration and clinician confidence in microbiome ecosystem therapies.

If approved, MaaT013 could help establish a new therapeutic category in hemato-oncology supportive care. The broader industry question is whether microbiome therapies can move from niche innovation into scalable, regulated treatment platforms for high-risk patients.