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Tecvayli plus Darzalex Faspro is granted FDA approval under the Commissioner's National Priority Voucher pilot program

Market Event Summary

Julia Morris, Ph.D. | March 2026

The FDA grants Tecvayli plus Darzalex Faspro approval for R/R multiple myeloma

Event

- On March 5, 2026, the **FDA approved Tecvayli plus Darzalex Faspro** for adults with **relapsed or refractory (R/R) multiple myeloma** who have received at least one prior line of therapy. This combination was filed on December 15, 2025, and has become the third approval under the new Commissioner's National Priority Voucher pilot program.
- This rapid approval was based on the Phase 3 **MajesTEC-3** trial, the results of which were presented at the 2025 American Society of Hematology Annual Meeting. Tecvayli plus Darzalex Faspro demonstrated **significant improvements in PFS (primary endpoint) and OS** compared with DPd or DVd (median PFS: NR vs. 18.1 months; HR 0.17; median OS: NR vs. NR; HR 0.46), with benefit observed across all prespecified subgroups.

Background

- **Tecvayli** (teclistamab) is a **bispecific monoclonal antibody** targeting **BCMA** and **CD3**. It first gained accelerated FDA approval in 2022 as a monotherapy in adult patients with R/R multiple myeloma who have received at least four prior lines of therapy. The FDA stated that this label will be converted to full approval, with the Phase 3 MajesTEC-3 combination data providing confirmatory evidence.
- Depending on the first-line therapy received, patients with second-line R/R multiple myeloma are typically treated with CD38-blocking monoclonal antibody-based regimens (i.e., DRd, DKd, Isa-Pd, DPd, DVd).

Clarivate's takeaways

Market outlook

The multiple myeloma market is highly dynamic, complex, and fragmented. In 2034, Clarivate forecasts Tecvayli sales of $2.2 billion. Collectively, BCMA-targeting agents will generate $10.2 billion in sales.

Ongoing trials

Tecvayli is being evaluated as a monotherapy in R/R multiple myeloma (Phase 3 **MajesTEC-9**), with Darzalex Faspro plus lenalidomide in first-line ASCT-ineligible patients (Phase 3 **MajesTEC-7**) and lenalidomide as post-ASCT maintenance in ASCT-eligible patients (Phase 3 **MajesTEC-4**).

Expected competition

Tecvayli plus Darzalex Faspro will face direct competition from Elrexfio plus Darzalex Faspro, which we expect to also receive approval in this setting in 2027, assuming the Phase 3 **MagnetisMM-5** trial is positive.

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About the author

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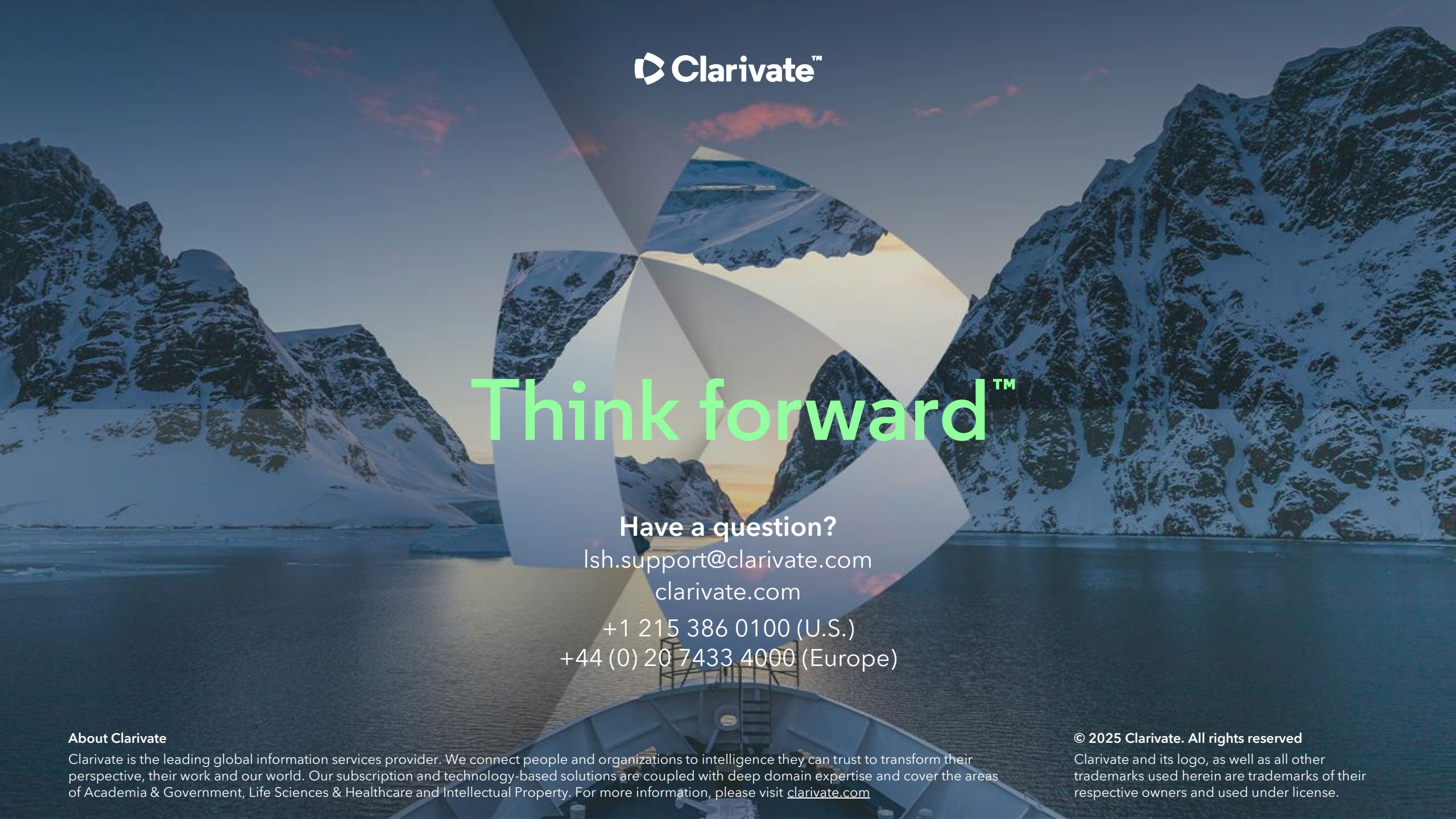
Julia Morris is a pharmaceutical industry analyst with over 10 years of experience in oncology research and drug discovery. Before joining Clarivate, Julia was a senior bioscientist in the Drug Discovery Unit at Cancer Research UK Manchester Institute. During this time, she developed and conducted assays to assess the effect of preclinical small-molecule inhibitors on in vitro cellular proliferation in breast, ovarian, and uterine cancer cell lines. She earned her Ph.D. in molecular biology from the University of Sheffield and a B.Sc. (Honors) in cellular and molecular medicine with study in industry from the University of Bristol.

Clarivate coverage of multiple myeloma

- Multiple Myeloma *Disease Landscape & Forecast (G7)*.
- Multiple Myeloma *China In-Depth*.
- Multiple Myeloma and Non-Hodgkin's Lymphoma: *Chimeric Antigen Receptor (CAR) T-cell Therapy Access & Reimbursement*.
- Multiple Myeloma *Current Treatment: Physician Insights (US)* - explores the prescribing trends of hematologist-oncologists treating multiple myeloma.
- Multiple Myeloma *Treatment Sequencing (US)* - presents surveyed hematologist-oncologists' most frequent treatment sequences for multiple myeloma.
- Multiple Myeloma *Unmet Need (US/EU)* – provides detailed and expanded analysis insights into areas of unmet need in specific subpopulations.



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