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Darzalex Faspro is the first FDA-approved therapy for high-risk smoldering multiple myeloma

Market Event Summary

Julia Morris, Ph.D. | November 2025

The FDA grants Darzalex Faspro approval for high-risk SMM

Event

- On November 6, 2025, the **FDA approved Darzalex Faspro** (subcutaneous daratumumab) for adults with **high-risk smoldering multiple myeloma (SMM)**. It is the **first and only** treatment for patients in this setting. The **EC approved** Darzalex Faspro for this patient population in July 2025.
- This approval was based on results from the Phase 3 **AQUILA** trial, in which Darzalex Faspro demonstrated a **significant improvement in PFS** compared with active monitoring in patients with Mayo 2018-classified high-risk SMM (median PFS: not reached vs. 22.1 months, HR 0.36). Additionally, the **median time to patients receiving first-line multiple myeloma treatment** was delayed compared with active monitoring (median TTFT: NR vs. 50.2 months, HR 0.46).

Background

- SMM is an early, asymptomatic stage of multiple myeloma. Before **Darzalex Faspro** was approved in this setting, high-risk SMM was managed through either **active surveillance (clinical observation)**, which involves testing at 3- to 6-month intervals, or enrollment in a clinical trial.
- Treating high-risk SMM is attractive from a clinical perspective because it can **delay progression to symptomatic disease** and potentially **extend survival**. However, some **interviewed physicians** remain **cautious** owing to the risk of **early resistance** and the possibility of **compromising future treatment options**. Using a therapy at the SMM stage may render it unavailable later, when it is most needed to treat symptomatic disease.
- **Darzalex Faspro**, a **CD38-blocking** monoclonal antibody, first received FDA approval in 2020.

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Clarivate's takeaways

Market outlook

The high-risk SMM population accounts for **33%** of the SMM population. Clarivate assumes that up to half of high-risk patients will receive drug treatment. We forecast Darzalex Faspro sales to reach **~$1.2 billion** in 2030.

Ongoing trials

Darzalex Faspro is being evaluated with VRd in the Phase 3 **CEPHEUS** trial for patients with first-line ASCT-ineligible multiple myeloma. It is also being evaluated in combination with lenalidomide in the Phase 3 **AURIGA** and **DRAMMATIC** trials for post-ASCT maintenance in ASCT-eligible patients.

Competition

The Phase 3 **ITHACA** trial is evaluating Sarclisa, lenalidomide, and dexamethasone in patients with high-risk SMM. KOLs favor this regimen given the success of lenalidomide and dexamethasone in the **QuiRedex** trial. If approved, Clarivate forecasts this regimen will partially cannibalize Darzalex Faspro use in this population.

About the author

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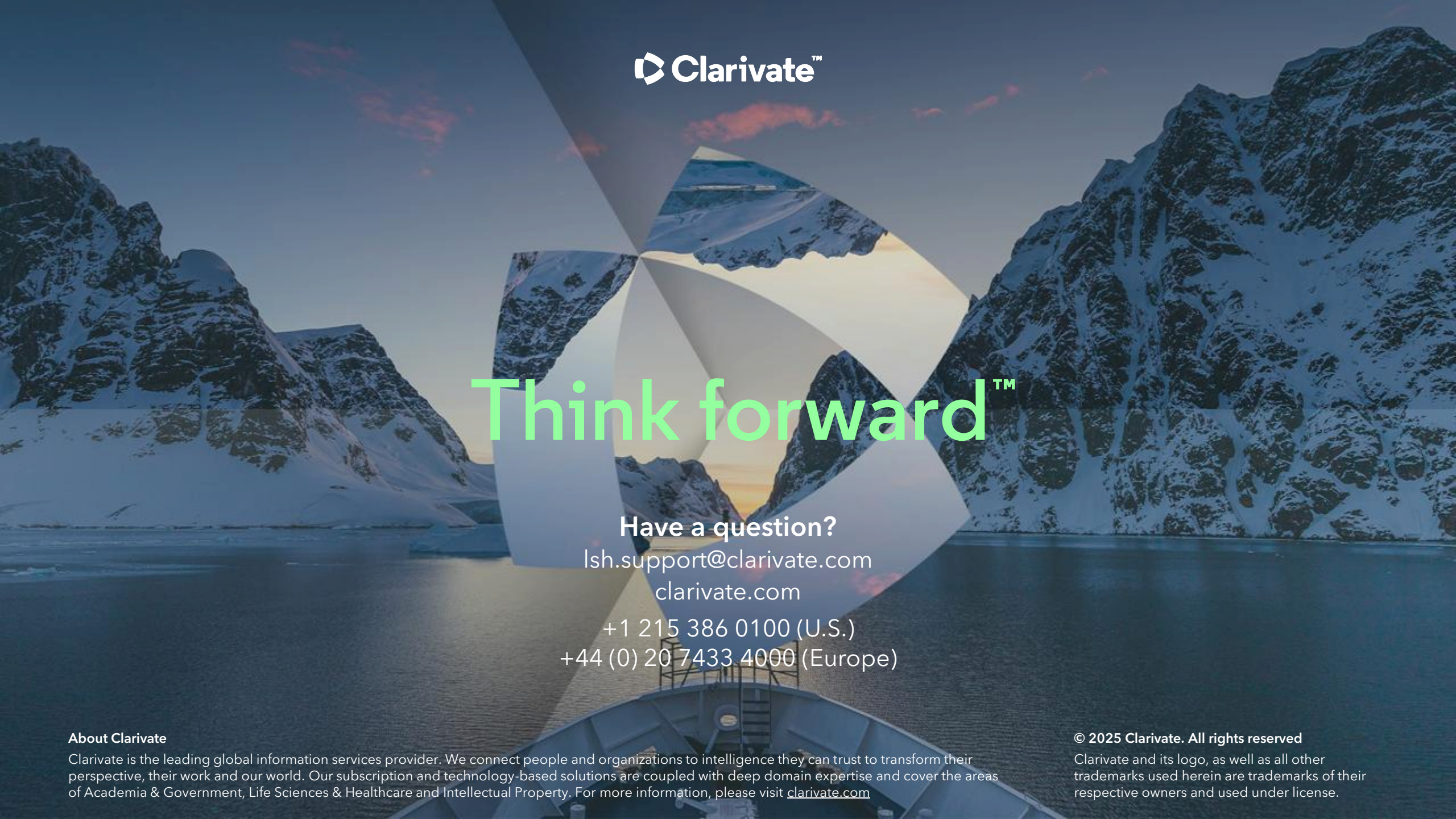
Julia Morris is a pharmaceutical industry analyst with over 10 years of experience in oncology research and drug discovery. Before joining Clarivate, Julia was a senior bioscientist in the Drug Discovery Unit at Cancer Research UK Manchester Institute. During this time, she developed and conducted assays 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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