GSK's Blenrep returns to the U.S. market with significant caveats

Market Event Summary

Julia Morris, Ph.D. | November 2025

The FDA grants restricted Blenrep approval, unlike Europe and Japan

Background

- Blenrep (belantamab mafodotin), a **BCMA-directed** monoclonal antibody linked to MMAF, received FDA accelerated approval in 2020 for **relapsed or refractory (R/R) multiple myeloma** patients who had received at least four prior therapies. This approval was based on Phase 2 **DREAMM-2** trial results. U.S. marketing authorization was **withdrawn** in 2023 following negative confirmatory data from the Phase 3 **DREAMM-3** trial.

Event

- On October 23, 2025, the **FDA approved Blenrep in combination with bortezomib and dexamethasone (Bela-Vd)** for adults with **R/R multiple myeloma** who have received at least two prior lines of therapy (**third line onward**), including a proteasome inhibitor and an immunomodulatory agent. Approval was based on Phase 3 **DREAMM-7** trial results. GSK sought approval for Bela-Vd from the second line onward, which was not granted.
- The FDA also rejected Blenrep in combination with pomalidomide and dexamethasone (**Bela-Pd**). In contrast, Bela-Vd and Bela-Pd received approval from the **second line onward** in Europe and Japan.
- The FDA ODAC voted 5–3 against Bela-Vd, citing limited U.S. enrollment (< 5%) and concerns that a safe and effective dose had not been established due to high rates of ocular toxicity. Consequently, the U.S. label includes a **boxed warning** for ocular toxicity and restricts access via the **BLENREP REMS** program.
- The **DREAMM-7** trial (Bela-Vd vs. DVd) reported a median PFS of 36.6 vs. 13.4 months (HR: 0.41, P < 0.00001). Although median OS was not reached in either arm, results significantly favored Bela-Vd (HR 0.58, P = 0.00023).

Clarivate™

Clarivate's takeaways

Market outlook

The R/R multiple myeloma market is highly dynamic, complex, and fragmented. In 2034, Clarivate forecasts Blenrep sales of $700 million. Collectively, in 2034 BCMA-targeting agents will generate $9.3 billion in sales.

Ongoing trials

Blenrep is in Phase 3 development in combination with lenalidomide and dexamethasone (Bela-Rd) for first-line ASCT-ineligible patients in the DREAMM-10 trial. This trial is expected to support a future approval, underscoring GSK's continued confidence in the therapy.

Competition

Blenrep will face strong competition from BCMA-targeting CAR T-cell therapies (ciltacabtagene autoleucel and idecabtagene vicleucel) and BiTEs (elranatamab, teclistamab, and linvoseltamab). Although BiTEs are in Phase 3 trials for earlier-line use, Blenrep may be preferred in certain circumstances for its simpler dosing.

About the author

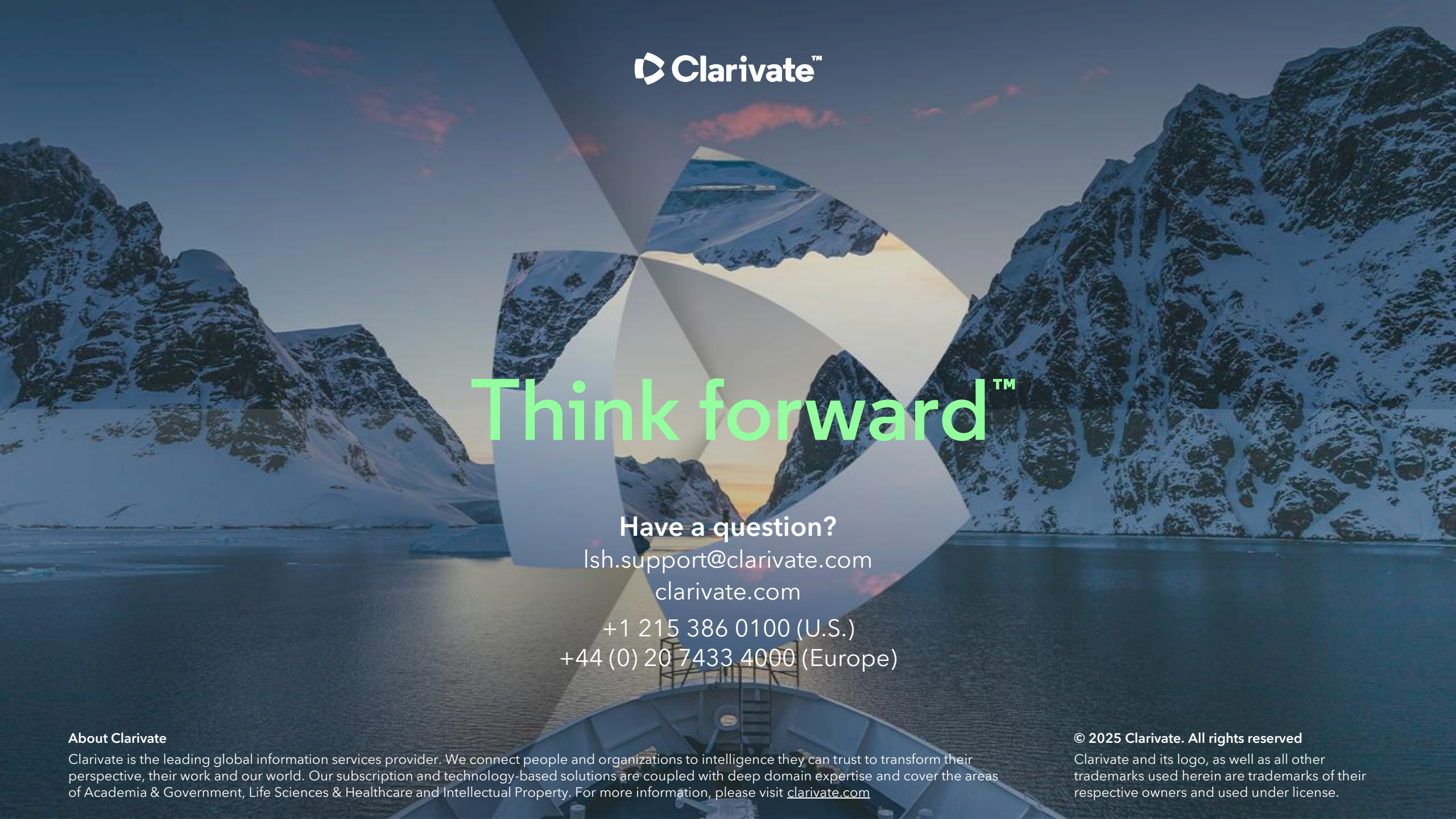
Julia Morris, Ph.D.

Healthcare Research & Data Analyst (Oncology)

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 *Disease Landscape & Forecast (China)*.
- 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.



About Clarivate

Clarivate is the leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit clarivate.com