

Regeneron's Bispecific Antibody Odronextamab Falls Short on FDA Regulatory Requirements

Market Event Summary

FDA increases scrutiny of accelerated approvals, demands updates from confirmatory trials

Background

Regeneron's odronextamab is an off-the-shelf IgG4 bispecific antibody (BsAb) designed to kill tumors by linking and activating CD3-binding cytotoxic T cells with CD20-binding cancer cells.

In September 2023, the FDA granted priority review to odronextamab's BLA for relapsed / refractory follicular lymphoma (R/R FL) and R/R diffuse large B-cell lymphoma (DLBCL) based on promising data from the Phase 2 ELM-2 and Phase 1 ELM-1 studies.

All currently marketed CD20/CD3 BsAbs entered the market with accelerated approval: Lunsumio for the treatment of R/R FL in 2022 and Epkinly and Columvi for R/R DLBCL in 2023.

Event

Odronextamab was poised to become the first BsAb approved for both FL and DLBCL, but the FDA issued a CRL for both indications. **For the first time, the CRLs specifically highlighted enrollment issues in the confirmatory trials.**

Regeneron had initiated an ambitious clinical development program (OLYMPIA) that included multiple Phase 3 trials. **The program aimed to redefine the treatment approach to NHL, extending its impact to first-line therapy.**

The FDA's requirement to include both dose-finding and confirmatory portions in the trials posed a challenge. Although enrollment in the dose-finding portion of the trial had begun, **the CRLs underscored the necessity for confirmatory portion to be under way with agreed timelines before BLA submission.**

Strategic implications



Delayed market entry: These CRLs push odronextamab's launch beyond 2024, causing the drug to fall further behind the already approved CD20/CD3 BsAbs.



Lacks distinction from competitors: Odronextamab shows no significant differentiation from existing options and lacks advantages offered by competitors, such as Epkinly's subcutaneous delivery and Columvi's fixed-duration treatment.



Path forward: The CRLs issued to odronextamab set a crucial precedent for future oncology therapies. They signal stricter requirements for accelerated approval requests, potentially impacting approvals based on early-phase clinical trials.

About the Author



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Clarivate coverage of Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia

- [NHL / CLL Disease Landscape & Forecast \(G7\)](#).
- [NHL / CLL Current Treatment: Physician Insights: US](#) explores the current prescribing trends of medical oncologists treating NHL / CLL.
- [NHL / CLL Current Treatment: Treatment Sequencing: US](#) presents surveyed medical oncologists' most frequent treatment sequences for NHL / CLL.
- [NHL / CLL Unmet Need](#) provides a detailed, expanded analysis of the unmet needs in the treatment of relapsed/refractory NHL / CLL.

Author Bio

Saurabh Virdi, B.Tech., is a lead analyst on the Oncology team at Clarivate. He has many years' experience in the pharmaceutical industry, providing analytical support in various therapy areas, including oncology, HIV, vaccines, specialty pharma, and rare diseases. Prior to joining Clarivate, he was an assistant project manager at DelveInsight Business Research LLP, where he was responsible for developing and delivering customized market and asset value forecasts. Before DelveInsight, he worked at WNS GSK Knowledge Center and SmartAnalyst, where, as part of multifunctional teams, he helped clients' decision making throughout the development journey from early-stage to marketed drugs. He holds a bachelor's degree in biotechnology from Delhi Technological University in India.



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