



Odronextamab BLA for Treatment of Relapsed/Refractory Follicular Lymphoma (FL) and Diffuse Large B-cell Lymphoma (DLBCL) Accepted for FDA Priority Review

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If approved, odronextamab would be the first and only bispecific antibody approved in both FL and DLBCL – the two most common subtypes of non-Hodgkin lymphoma

European Medicines Agency also reviewing odronextamab Marketing Authorization Application

TARRYTOWN, N.Y., Sept. 29, 2023 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the Biologics License Application (BLA) for odronextamab to treat adult patients with relapsed/refractory (R/R) follicular lymphoma (FL) or R/R diffuse large B-cell lymphoma (DLBCL), who have progressed after at least two prior systemic therapies. The target action date for the FDA decision is March 31, 2024. Odronextamab is an investigational CD20xCD3 bispecific antibody designed to bridge CD20 on cancer cells with CD3-expressing T cells to facilitate local T-cell activation and cancer-cell killing.

The BLA was supported by data from a Phase 1 and pivotal Phase 2 trial (ELM-1 and ELM-2). Results from these studies investigating odronextamab in both [FL](#) and [DLBCL](#) were last presented at the 64th American Society of Hematology Annual Meeting.

The FDA previously granted odronextamab Orphan Drug Designation and Fast Track Designation for FL and DLBCL. In [August](#), the European Medicines Agency accepted for review a Marketing Authorization Application for odronextamab for the treatment of adult patients with R/R FL or R/R DLBCL who have progressed after at least two prior systemic therapies.

FL and DLBCL are the two most common subtypes of B-cell non-Hodgkin lymphoma (B-NHL). FL is a slow-growing subtype, and although many patients are responsive to initial treatment, approximately 20% are expected to relapse within two years and have shorter remissions with each successive line of therapy. DLBCL is an aggressive subtype, with up to 50% of high-risk patients experiencing progression after first-line treatment (e.g., relapsing or refractory to treatment). As these blood cancers progress, they become increasingly hard to treat, especially in the third-line setting and beyond, leaving patients with few treatment options.

Odronextamab is currently under clinical development, and its safety and efficacy have not been fully evaluated by any regulatory authority.

About the Odronextamab Clinical Program

ELM-1 is an ongoing, open-label, multicenter Phase 1 trial to investigate the safety and tolerability of odronextamab in patients with CD20+ B-cell malignancies previously treated with CD20-directed antibody therapy, including an expansion cohort evaluating DLBCL patients who had progressed on CAR-T therapy (post-CAR-T). ELM-2 is an ongoing, open-label, multicenter pivotal Phase 2 trial investigating odronextamab in 375 patients across five independent disease-specific cohorts, including DLBCL, FL, mantle cell lymphoma, marginal zone lymphoma and other subtypes of B-NHL. The primary endpoint of ELM-2 is objective response rate according to the Lugano Classification, and secondary endpoints include complete response, progression-free survival, overall survival, duration of response, disease control rate, safety and quality of life.

Regeneron is also initiating a broad Phase 3 development program to investigate odronextamab in earlier lines of therapy and other B-NHLs, representing one of the largest clinical programs in lymphoma.

About Regeneron's Approach to Cancer Research

At Regeneron, we're applying more than three decades of scientific innovation with the goal of developing paradigm-changing therapies for patients with cancer.

Our portfolio is built around two foundational approaches – our approved PD-1 inhibitor Libtayo® (cemiplimab-rwlc) and investigational bispecific antibodies – which are being evaluated both as monotherapies and in combination with emerging therapeutic modalities. Together, they provide us with unique combinatorial flexibility to develop potentially synergistic treatments for a wide range of solid tumors and blood cancers.

If you are interested in learning more about our clinical trials, please contact us (clinicaltrials@regeneron.com or 1-844-734-6643) or visit our clinical trials [website](#).

About Regeneron

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for 35 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous FDA-approved treatments and product candidates in development, almost all of which were homegrown in our laboratories. Regeneron's medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, hematologic conditions, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its proprietary *VelociSuite*[®] technologies, such as *VelocImmune*[®], which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through ambitious research initiatives such as the Regeneron Genetics Center[®], which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about Regeneron, please visit www.regeneron.com or follow Regeneron on [LinkedIn](#).

Forward-Looking Statements and Use of Digital Media

This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation odronextamab; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, such as odronextamab for the treatment of adult patients with relapsed/refractory follicular lymphoma or relapsed/refractory diffuse large B-cell lymphoma (including based on the Biologics License Application discussed in this press release); uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates (such as odronextamab); the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manage supply chains for multiple products and product candidates; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates (such as odronextamab) in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement of Regeneron's Products from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license, collaboration, or supply agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable) to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on Regeneron's business; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA[®] (afibercept) Injection and REGEN-COV[®] (casirivimab and imdevimab)), other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2022 and its Form 10-Q for the quarterly period ended June 30, 2023. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<https://investor.regeneron.com>) and its LinkedIn page (<https://www.linkedin.com/company/regeneron-pharmaceuticals>).

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