



Odronextamab BLA Accepted for FDA Review for the Treatment of Relapsed/Refractory Follicular Lymphoma

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FDA decision expected by July 30, 2025

TARRYTOWN, N.Y., Feb. 26, 2025 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the resubmission of the Biologics License Application (BLA) for odronextamab in relapsed/refractory (R/R) follicular lymphoma (FL) after two or more lines of systemic therapy. The target action date for the FDA decision is July 30, 2025.

Acceptance of the BLA resubmission follows the achievement of an FDA-mandated enrollment target for the Phase 3 confirmatory trial in FL (OLYMPIA -1). This was the sole approvability issue identified by the FDA in the complete response letter associated with the previous submission. The BLA resubmission is supported by data from the Phase 1 and pivotal Phase 2 trials (ELM-1 and ELM-2), which demonstrated an overall response rate of 80% (n=103), with 74% (n=95) achieving a complete response. Serious adverse events occurred in 67% of patients; those occurring in ≥10% of patients included cytokine release syndrome, COVID-19 and pneumonia.

Odronextamab is [approved](#) as Ordspono™ in the European Union for the treatment of R/R FL or diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy although its safety and efficacy have not been fully evaluated by any other regulatory authority. For complete product information, please see the Summary of Product Characteristics that can be found on www.ema.europa.eu.

About FL

FL is one of the most common subtypes of B-cell non-Hodgkin lymphoma (B-NHL). While FL is a slow-growing subtype, it is an incurable disease, and most patients will relapse after initial treatment. It is estimated that approximately 122,000 FL cases are diagnosed globally every year with more than 13,600 FL cases anticipated in the U.S. in 2025.

About the Odronextamab Clinical Development Program

Odronextamab is a 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.

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.

ELM-2 is an ongoing, open-label, multicenter Phase 2 trial investigating odronextamab across five independent disease-specific cohorts, including DLBCL, FL, mantle cell lymphoma, marginal zone lymphoma and other subtypes of B-NHL. The primary endpoint is objective response rate according to the Lugano Classification as assessed by independent review committee, and secondary endpoints include complete response, progression-free survival, overall survival and duration of response. The pivotal results in FL were published in the [Annals of Oncology](#).

Odronextamab is being investigated in a broad clinical development program exploring its use as a monotherapy as well as in combination regimens in several types of B-NHLs in earlier lines of therapy. In FL, odronextamab is being evaluated as a monotherapy against rituximab plus standard-of-care chemotherapies in a Phase 3 confirmatory trial ([OLYMPIA -1](#)) and in combination with chemotherapy against rituximab plus standard-of-care chemotherapies in a separate Phase 3 trial ([OLYMPIA -2](#)). For more information on Regeneron's clinical trials in blood cancer, visit the clinical trials [website](#) or contact via clinicaltrials@regeneron.com or +1 844-734-6643.

About Regeneron in Hematology

At Regeneron, we're applying more than three decades of biology expertise with our proprietary *VelociSuite*® technologies to develop medicines for patients with diverse blood cancers and rare blood disorders.

Our blood cancer research is focused on bispecific antibodies that are being investigated both as monotherapies and in various combinations and emerging therapeutic modalities. Together, they provide us with unique combinatorial flexibility to develop customized and potentially synergistic cancer treatments.

Our research and collaborations to develop potential treatments for rare blood disorders include explorations in antibody medicine, gene editing and gene-knockout technologies, and investigational RNA-approaches focused on depleting abnormal proteins or blocking disease-causing cellular signaling.

About Regeneron's VelocImmune® Technology

Regeneron's VelocImmune technology utilizes a proprietary genetically engineered mouse platform endowed with a genetically humanized immune system to produce optimized fully human antibodies. When Regeneron's co-Founder, President and Chief Scientific Officer George D. Yancopoulos was a graduate student with his mentor Frederick W. Alt in 1985, they were the first to [envision](#) making such a genetically humanized mouse, and Regeneron has spent decades inventing and developing VelocImmune and related VelociSuite technologies. Dr. Yancopoulos and his team have used VelocImmune technology to create a substantial proportion of all original, FDA-approved fully human monoclonal antibodies. This includes Dupixent® (dupilumab), Libtayo® (cemiplimab-rwlc), Praluent® (alirocumab), Kevzara® (sarilumab), Evkeeza® (evinacumab-dgnb), Inmazeb® (atoltivimab, maftivimab and odesivimab-ebgn) and Veopoz® (pozelimab-bbfg). In addition, REGEN-COV® (casirivimab and imdevimab) had been authorized by the FDA during the COVID-19 pandemic until 2024.

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 by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as VelociSuite, which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on [LinkedIn](#), [Instagram](#), [Facebook](#) or [X](#).

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 relapsed/refractory ("R/R") follicular lymphoma (including in the United States based on the Biologics License Application ("BLA") resubmission discussed in this press release) or the other clinical development programs investigating odronextamab as referenced in this press release; whether the achievement of a prespecified target for enrollment in the Phase 3 confirmatory trial of odronextamab discussed in this press release will be sufficient for purposes of potential approval of the resubmitted BLA for odronextamab in R/R follicular lymphoma by the U.S. Food and Drug Administration; 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; changes in laws, regulations, and policies affecting the healthcare industry; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including biosimilar versions of Regeneron's Products); 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 on

Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), 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), 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, 2024. 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>).

Note: An update has been made to correct the description of the Phase 3 confirmatory trial on March 7, 2025

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