Linvoseltamab BLA Accepted for FDA Review for the Treatment of Relapsed/Refractory Multiple Myeloma

February 11, 2025 at 7:00 AM EST

Acceptance follows resolution of third-party fill/finish manufacturing issues

FDA decision expected by July 10, 2025

TARRYTOWN, N.Y., Feb. 11, 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 linvoseltamab for the treatment of adult patients with relapsed/refractory (R/R) multiple myeloma (MM) who have received at least four prior lines of therapy or those who received three prior lines of therapy and are refractory to the last line of therapy. The target action date for the FDA decision is July 10, 2025.

Acceptance of the BLA resubmission follows the resolution of third-party fill/finish manufacturing issues, which was the sole approvability issue identified by the FDA in the previous submission. The BLA is supported by data from the pivotal LINKER-MM1 trial investigating linvoseltamab in R/R MM, and linvoseltamab is also under review by the European Medicines Agency (EMA) for the same patient population.

Linvoseltamab is investigational and has not been approved by any regulatory authority.

About Multiple Myeloma
As the second most common blood cancer, there are over 187,000 new cases of MM diagnosed globally every year, with more than 36,000 diagnosed and 12,000 deaths anticipated in the U.S. in 2025. In the U.S., there are approximately 8,000 people who have MM that has progressed after three lines of therapy, and 4,000 whose disease has progressed after four or more therapies. The disease is characterized by the proliferation of cancerous plasma cells (MM cells) that crowd out healthy blood cells in the bone marrow, infiltrate other tissues and cause potentially life-threatening organ injury. Despite treatment advances, MM is not curable and while current treatments are able to slow progression of the cancer, most patients will ultimately experience cancer progression and require additional therapies.

About the Linvoseltamab Clinical Development Program
Linvoseltamab is an investigational BCMAxCD3 bispecific antibody designed to bridge B-cell maturation antigen (BCMA) on MM cells with CD3-expressing T cells to facilitate T-cell activation and cancer-cell killing.

The ongoing, open-label, multicenter Phase 1/2 dose-escalation and dose-expansion LINKER-MM1 trial is investigating linvoseltamab in 282 enrolled patients with relapsed/refractory MM. The Phase 1 dose-escalation portion of the trial – which is now complete – primarily assessed safety, tolerability and dose-limiting toxicities across nine dose levels of linvoseltamab and explored different administration regimens. The ongoing Phase 2 dose expansion portion is assessing the safety and anti-tumor activity of linvoseltamab, with the primary endpoint of objective response rate. Key secondary endpoints include duration of response, progression-free survival, rate of minimum residual disease negative status and overall survival.

Eligibility in the Phase 2 portion requires patients to have received at least three prior lines of therapy or have triple-class refractory MM. Linvoseltamab is administered with an initial step-up dosing regimen followed by the full 200 mg dose administered weekly. At week 16, all patients transition to every two-week dosing. A response-adapted regimen further enables patients to shift to every four-week dosing if they achieve a very good partial response or better and have completed at least 24 weeks of therapy. The regimen requires a total of two 24-hour hospitalizations for safety monitoring.

Linvoseltamab is being investigated in a broad clinical development program exploring its use as a monotherapy as well as in combination regimens across different lines of therapy in MM, including earlier lines of treatment, as well as plasma cell precursor disorders. They include evaluating linvoseltamab in a Phase 1b trial (LINKER-MM2) in combination with other cancer treatments in R/R MM as well as a Phase 3 confirmatory trial (LINKER-MM3) as a monotherapy in R/R MM. For more information on Regeneron's clinical trials in blood cancer, visit the clinical trials website, or contact via clinicaltrials@regeneron.com or 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 linvoseltamab; 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 linvoseltamab for the treatment of relapsed/refractory ("R/R") multiple myeloma (including in the United States based on the Biologics License Application ("BLA") resubmission discussed in this press release or in the European Union as referenced in this press release); whether the resolution of the third-party fill/finish manufacturing issues discussed in this press release will be sufficient for purposes of potential approval of the resubmitted BLA for linvoseltamab in R/R multiple myeloma 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 linvoseltamab); 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 linvoseltamab) 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 (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® (aflibercept) 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).

Contacts:

Media Relations
Tammy Allen
Tel: +1 914-306-2698
tammy.allen@regeneron.com

Investor Relations
Mark Hudson
Tel: +1 914-847-3482
mark.hudson@regeneron.com

REGENERON

Source: Regeneron Pharmaceuticals, Inc.