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

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TARRYTOWN, N.Y., Feb. 21, 2024 (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 linvoseltamab to treat adult patients with relapsed/refractory (R/R) multiple myeloma (MM) that has progressed after at least three prior therapies. The target action date for the FDA decision is August 22, 2024. Linvoseltamab is an investigational bispecific antibody designed to bridge B-cell maturation antigen on multiple myeloma cells with CD3-expressing T cells to facilitate T-cell activation and cancer-cell killing.

The BLA is supported by data from a Phase 1/2 pivotal trial (LINKER-MM1) investigating linvoseltamab in R/R MM, which were last shared in December 2023. Earlier this month, the European Medicines Agency accepted for review the Marketing Authorization Application for linvoseltamab in the same indication.

As the second most common blood cancer, it's estimated 35,000 people will be diagnosed with MM in the U.S. every year. MM 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. MM is not curable despite treatment advances. While current treatments are able to slow the progression of the cancer, most patients will ultimately experience disease progression and require additional therapies.

The linvoseltamab clinical development program includes a Phase 3 confirmatory trial in patients with R/R MM (LINKER-MM3) that is currently enrolling. Additional trials in earlier lines of therapy and stages of disease are planned or underway, including a Phase 1/2 trial in the first-line setting, a Phase 2 trial in high-risk smoldering MM and a Phase 2 trial in monoclonal gammopathy of undetermined significance. A Phase 1 trial of linvoseltamab in combination with a Regeneron CD38xCD28 costimulatory bispecific in MM is also planned. For more information, visit the Regeneron clinical trials website, or contact via clinicaltrials@regeneron.com or 844-734-6643.

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

About the Phase 1/2 Trial
The ongoing, open-label, multicenter Phase 1/2 dose-escalation and dose-expansion LINKER-MM1 trial is investigating linvoseltamab in 282 enrolled patients with R/R MM. Eligibility in the Phase 2 portion required patients to have received at least three prior lines of therapy or have triple-class refractory MM. Linvoseltamab was administered with an initial step-up dosing regimen followed by the full dose. Additionally, in the Phase 2 portion, a response-adapted regimen enabled patients treated with linvoseltamab 200 mg who achieved a very good partial response or a complete response to shift from every two-week to every four-week dosing after a minimum of 24 weeks of therapy.

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 exploring different administration regimens. The Phase 2 dose expansion portion is assessing the safety and anti-tumor activity of linvoseltamab, with a primary endpoint of objective response rate. Key secondary endpoints include duration of response, progression free survival, rate of minimal residual disease negative status and overall survival.

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
Regeneron is a leading biotechnology company that invents, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led for over 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. Our 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 our 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 more 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 linvoseltamab for the treatment of relapsed/refractory ("R/R") multiple myeloma ("MM"); 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 R/R MM (including based on the Biologics License Application or the Marketing Authorization Application discussed or referenced 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 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; 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® (aflibercept) Injection), 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, 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).

Contacts:

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

Investor Relations
Vesna Tosic
Tel: +1 914-847-5443
vesna.tosic@regeneron.com

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