Regeneron Provides Update on Biologics License Application for Odronextamab

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TARRYTOWN, N.Y., March 25, 2024 (GLOBE NEWSWIRE) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that the U.S. Food and Drug Administration (FDA) has issued Complete Response Letters (CRLs) for the Biologics License Application (BLA) for odronextamab in relapsed/refractory (R/R) follicular lymphoma (FL) and in R/R diffuse large B-cell lymphoma (DLBCL), each after two or more lines of systemic therapy. The only approvability issue is related to the enrollment status of the confirmatory trials. The CRLs – one for R/R FL and one for R/R DLBCL – did not identify any approvability issues with the odronextamab clinical efficacy or safety, trial design, labeling or manufacturing.

Regeneron has been actively enrolling patients in multiple Phase 3 trials for odronextamab as part of the OLYMPIA program – one of the largest clinical programs in lymphoma. As the OLYMPIA program is intended to change the treatment paradigm of several B-cell non-Hodgkin lymphoma subtypes – including in earlier lines of therapy – in agreeing to the program, the FDA required that the trials include both dose-finding and confirmatory portions. Enrollment in the dose-finding portion has begun, but the CRLs indicate that the confirmatory portions of these trials should be underway and that the timelines to completion be agreed prior to resubmission. Regeneron is committed to working closely with the FDA and investigators to bring odronextamab to patients with R/R FL and R/R DLBCL as quickly as possible. Regeneron plans on sharing updates on enrollment and regulatory timelines later this year.

Regulatory review of odronextamab remains ongoing by the European Medicines Agency (EMA) for the treatment of R/R DLBCL and R/R FL. In the European Union, odronextamab was granted Orphan Drug Designation in DLBCL and FL.

The potential use of odronextamab in R/R DLBCL and R/R FL is currently under clinical development and has not been approved by any regulatory authority.

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 odronextamab; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates (such as odronextamab, including any potential regulatory approval of odronextamab by the U.S. Food and Drug Administration (the "FDA") based on the Biologics License Application discussed in this press release (the "odronextamab BLA") or the regulatory review by the European Medicines Agency referenced in this press release) and new indications for Regeneron's Products; the impact of the Complete Response Letters for the odronextamab BLA discussed in this press release (the "CRLs") on the timing of the potential regulatory approval of odronextamab by the FDA and whether and how timely Regeneron is able to resolve the issues identified in the CRLs (including Regeneron's ability to enroll patients in the confirmatory portions of the Phase 3 trials for odronextamab referenced in this press release); uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates (such as odronextamab) and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on any of the foregoing or any potential regulatory approval of Regeneron's Products and Regeneron's Product Candidates; 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® (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).

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