Regeneron to Report Results from CD20xCD3 and BCMAxCD3 Bispecifics and C5 Antibody Programs at ASH Annual meeting

November 6, 2019

New data is from programs in B-cell non-Hodgkin lymphoma, multiple myeloma and paroxysmal nocturnal hemoglobinuria

TARRYTOWN, N.Y., Nov. 6, 2019 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that it will share new and updated data for two investigational medicines for blood cancers and a third for a rare blood disease at the 2019 American Society of Hematology (ASH) Annual Meeting from December 7-10 in Orlando, FL.

Among the accepted abstracts are the first clinical data for REGN5458 (BCMAxCD3) in relapsed/refractory (R/R) multiple myeloma, as well as updated data for REGN1979 (CD20xCD3) in R/R B-cell non-Hodgkin lymphoma (B-NHL). Beyond oncology, the company will share data on pozelimab, a monoclonal antibody designed to block complement factor C5 and prevent the destruction of red blood cells (hemolysis) that cause the symptoms of paroxysmal nocturnal hemoglobinuria (PNH).

"The ASH presentations highlight Regeneron's growing portfolio in blood cancer and rare diseases, including data from two of our six bispecific antibodies currently in clinical development," said David Weinreich, M.D., Senior Vice President, Head of Global Clinical Development and Co-Head of Global Development at Regeneron. "We will also present data on pozelimab, which we are studying in a Phase 2 program in paroxysmal nocturnal hemoglobinuria."

"We continue to make important progress with REGN1979 and are currently enrolling a potentially registrational Phase 2 trial. At ASH, we plan to share new data with additional patients and longer duration of follow-up, with about 20 patients at effective dose levels for each cohort of follicular lymphoma and diffuse large B-cell lymphoma," said Israel Lowy, M.D., PhD, Senior Vice President and Head of Clinical and Translational Sciences for Oncology at Regeneron. "As part of our expanding bispecific portfolio, we will also present encouraging, early single-agent data on REGN5458, our BCMAxCD3 bispecific for multiple myeloma. Additional investigational bispecific antibodies are expected to enter clinical trials in the coming year."

The abstracts published today reflect older data; presentations with updated data will be shared at ASH as follows:

REGN1979

- Oral presentation: Clinical Activity of REGN1979, a Bispecific Human, Anti-CD20xAnti-CD3 Antibody, in Patients with Relapsed/Refractory (R/R) B-cell Non-Hodgkin Lymphoma (B-NHL) (Abstract 762; Rajat Bannerji, M.D., Ph.D.: Monday, December 9, 2:45-4:15 PM ET)
- Poster presentation: A Phase 2 Study of REGN1979, an Anti-CD20xAnti-CD3 Bispecific Antibody (Ab), in Patients with Relapsed/Refractory (R/R) B-Cell Non-Hodgkin Lymphoma (B-NHL) (Abstract 4007, Max S. Topp, M.D.: Monday, December 9, 6:00-8:00 PM ET)

REGN5458

- Poster presentation: Safety and Preliminary Clinical Activity of REGN5458, an Anti-BCMAxAnti-CD3 Bispecific Antibody, in Patients with Relapsed/Refractory (R/R) Multiple Myeloma (Abstract 3176; Dennis Cooper, M.D.: Sunday, December 8, 6:00-8:00 PM ET)

Pozelimab/PNH

- Oral presentation: A Novel Patient Reported Outcome Instrument Assessing the Symptoms of Paroxysmal Nocturnal Hemoglobinuria (Abstract 385; R Paola Daly: Sunday, December 8, 7:30-9:00 AM ET)
- Poster presentation: Pozelimab, a Human Antibody Against Complement Factor C5, Demonstrates Robust Inhibition of Alternative Complement Activity Both in Normal Human Serum and in Phase I Normal Healthy Volunteers (Abstract 2278; Kishor Devalaraja-Narashimha, Ph.D., DVM: Sunday, December 8, 6:00-8:00 PM ET)
- Poster presentation: Epidemiology of PNH and Real-World Treatment Patterns Following Incident PNH Diagnosis in the U.S. (Abstract 3407; Jessica J Jalbert, Ph.D.: Sunday, December 8, 6:00-8:00 PM ET)

About the Regeneron Bispecific Antibody Platform

All of Regeneron's bispecific antibodies are designed to closely resemble natural human antibodies. They are derived from a next-generation version of Regeneron's proprietary *VelocImmune*® technology and created using the company's *VelociBi* ™ platform.

There are six Regeneron investigational bispecific antibodies currently in ongoing clinical trials for multiple blood cancers and solid tumors. These bispecifics fall into three categories:

- **CD3 bispecifics** are designed to bridge T-cells and tumor cells. At the tumor site, they activate T-cells via their CD3

receptors and promote T-cell killing of the cancer cells. Investigational candidates include:
    - CD20xCD3 (REGN1979) for non-Hodgkin B-cell lymphomas;
    - Two distinct BCMAxCD3s (REGN5458 and REGN5459) for multiple myeloma;
    - MUC16xCD3 (REGN4018) for ovarian cancer.
- **CD28 costimulatory bispecifics** are also designed to bridge T-cells and tumor cells. At the tumor site, they costimulate T-cells via their CD28 receptors and may synergize with PD-1 inhibitors and/or CD3 bispecifics. Investigational candidates include:
    - PSMAxCD28 (REGN5678) in combination with Libtayo® (cemiplimab) for prostate cancer.
- **Tumor-targeted bispecifics** are designed to target proteins only on the cancer cell. In this way, they may affect various signaling pathways to hamper the cancer cells' ability to survive and proliferate. Investigational candidates include:
    - METxMET (REGN5093) for non-small cell lung cancer that is driven by MET mutations and/or amplifications. REGN5093 targets two different parts of the MET receptor on cancer cells to degrade the receptor and block its ability to trigger cell proliferation.

Regulatory Status of Programs
REGN1979, REGN5458, REGN5459, REGN4018, REGN5678, REGN5093, pozelimab and Libtayo are currently under clinical development for the diseases noted in this press release, and their safety and efficacy have not been evaluated by any regulatory authority for these diseases. As part of a global collaboration agreement, Regeneron and Sanofi are jointly developing Libtayo, as well as Regeneron's BCMAxCD3 and MUC16xCD3 bispecific programs.

Libtayo is approved in the U.S. for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation, and in other countries for similar indications. In the U.S., the generic name for Libtayo is cemiplimab-rwlc, with rwlc as the suffix designated in accordance with Nonproprietary Naming of Biological Products Guidance for Industry issued by the U.S. Food and Drug Administration.

About Regeneron Pharmaceuticals, Inc.
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to seven FDA-approved treatments and numerous product candidates in development, 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, infectious diseases, pain and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*®, which uses a unique genetically-humanized mouse 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 the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Regeneron 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 Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation REGN1979 in patients with relapsed or refractory B-cell non-Hodgkin lymphoma and other potential indications, as well as REGN5458 (BCMAxCD3 bispecific antibody being investigated in multiple myeloma) and pozelimab (C5 antibody), and Regeneron's earlier-stage product candidates (such as Regeneron's other bispecific antibodies and costimulatory bispecific antibody discussed in this press release (as a monotherapy or in combination with Libtayo® (cemiplimab), as applicable)); unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates (such as REGN1979, REGN5458, and pozelimab) in clinical trials; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; 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 product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product candidates; the availability and extent of reimbursement of the Company'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; 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 or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated without any further product success; 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 Dupixent® (dupilumab) and Praluent® (alirocumab)), 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 fiscal year ended December 31, 2018 and its Form 10-Q for the quarterly period ended September 30, 2019. 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 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 (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

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