Regeneron Collaboration Programs Highlighted During Sanofi Analyst Day

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TARRYTOWN, N.Y., Dec. 13, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced updates related to its collaboration programs with Sanofi, which were highlighted during Sanofi's Sustaining Innovation Analyst Day in Paris, France.

In a separate release today the companies also shared positive topline results for PD-1 antibody cemiplimab in advanced cutaneous squamous cell carcinoma (CSCC).

Immunology and Inflammation: Dupixent® (dupilumab) and IL-33 antibody

- A supplemental Biologics License Application (sBLA) for dupilumab in persistent, uncontrolled asthma is expected to be submitted in the fourth quarter of 2017.
- In 2018, a Dupixent® (dupilumab) sBLA submission is planned for atopic dermatitis in adolescents ages 12 to 17, and in 2019, a second sBLA is planned for children ages 6 to 12.
- In 2019, an sBLA is planned for dupilumab in adults with nasal polyposis.
- Pivotal Phase 3 studies are planned for 2018 evaluating the use of dupilumab in chronic obstructive pulmonary disease (COPD), a condition for which there are no approved biologic therapies.
- A pivotal Phase 3 study is planned for 2018 evaluating the use of dupilumab in eosinophilic esophagitis (EoE), a condition for which there are no approved therapies in the U.S.
- Phase 2 studies investigating the use of dupilumab as an adjunctive therapy to immunotherapies for the treatment of peanut and grass allergy are planned for 2018.
- Dupilumab studies are planned for 2018 to evaluate patients with comorbid allergic inflammatory conditions.
- REGN3500, an antibody to IL-33, is currently being investigated in Phase 1b studies in adult patients with moderate asthma and mild allergic asthma both as monotherapy and in combination with dupilumab.
- In 2018, the companies plan to initiate Phase 2 proof-of-concept studies for REGN3500 in asthma and COPD, and a Phase 2b study in atopic dermatitis.

Immunology and Inflammation: Kevzara® (sarilumab)

- Phase 3 studies of sarilumab in giant cell arteritis and polymyalgia rheumatica are expected to be initiated in 2018.
- A Phase 2 study of sarilumab in systemic juvenile arthritis is also expected to begin in 2018.

Immuno-Oncology

- In the first quarter of 2018, the companies plan to submit a BLA to the FDA for cemiplimab (REGN2810, PD-1 antibody) for the lead indication of locally advanced and unresectable or metastatic CSCC.
- Further development plans for cemiplimab include ongoing studies in basal cell carcinoma and cervical cancer.
    - Three Phase 3 studies are either planned or underway in first-line non-small cell lung cancer (NSCLC):
        - Cemiplimab vs. platinum doublet in patients with PD-L1 expression greater than or equal to 50 percent (ongoing).
        - Cemiplimab in combination with ipilimumab or chemotherapy vs. platinum doublet in patients with PD-L1 expression less than 50 percent (initiated).
        - Cemiplimab in combination with ipilimumab or chemotherapy in patients with PD-L1 expression greater than or equal to 50 percent (planned).
    - A second-line study of cemiplimab in NSCLC is also planned.
- Regeneron is also advancing REGN3767, a LAG3 antibody, for cancer both as monotherapy and in combination with cemiplimab, as well as other preclinical immuno-oncology bispecific and monoclonal antibody therapies.

Cardiovascular Disease: Praluent® (alirocumab)

- Data from the ODYSSEY OUTCOMES trial evaluating PRALUENT® (alirocumab) are expected in the first quarter of 2018.
- The median duration of treatment in the ODYSSEY OUTCOMES study is 33 months, with some patients treated for up to five years.
- Based on data from ODYSSEY OUTCOMES, the companies anticipate submitting an sBLA to the FDA by the third quarter of 2018.

About Regeneron
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for nearly 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, including *VelocImmune*® to yield optimized fully-human antibodies, and ambitious initiatives such as the Regeneron Genetics Center, 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 news 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 Dupixent® (dupilumab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, and cemiplimab (REGN2810, an antibody to PD-1); 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 in clinical trials, such as Dupixent, Praluent, Kevzara, and cemiplimab; 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; 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, such as Dupixent, Praluent, Kevzara, and cemiplimab; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators (such as the clinical programs evaluating REGN3500, an antibody to IL-33; and REGN3767, an antibody to LAG-3) may be replicated in later studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research, and clinical programs (such as the clinical programs relating to Dupixent, Praluent, Kevzara, cemiplimab, REGN3500, and REGN3767 referenced in this news release), and business, including those relating to patient privacy; 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's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labelling, distribution, and other steps related to Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other 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 HealthCare LLC, 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 proceedings relating to Praluent, the ultimate outcome of any such litigation proceedings, 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 United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2016 and its Form 10-Q for the quarterly period ended September 30, 2017. 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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