REGENERON



Press Release

Regeneron and Sanofi Genzyme to Present Additional Data from Pivotal Phase 2b Dupilumab Study in Adults with Uncontrolled Persistent Asthma at the American Thoracic Society International Conference

Tarrytown, NY and Cambridge MA (May 11, 2016) -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi Genzyme today announced that additional data from the pivotal Phase 2b dupilumab study in adults with uncontrolled persistent asthma will be presented at the American Thoracic Society's (ATS) International Conference in San Francisco, California from May 13-18, 2016. In addition, the full results from the pivotal Phase 2b study were recently published online in *The Lancet*. The topline results of this study were <u>announced</u> in November 2014.

Four posters at ATS will highlight additional post-hoc analyses of quality of life and patient-reported outcomes data during the following poster sessions:

- Thematic Poster Session: May 15, 2016 9 a.m.-4:15 p.m. PT Area A, Hall D (North Building, Lower Level)
 - FEV1 Improvement with Dupilumab by Different Baseline Patient Characteristics in Patients with Uncontrolled Persistent Asthma
- Poster Discussion Session: May 18, 2016 9-11 a.m. PT Room 2010/2012 (West Building, Level 2)
 - Dupilumab Improves Patient-Reported Outcomes in Uncontrolled Persistent Asthma: Results from a Phase 2b Clinical Trial
 - Dupilumab Improves Lung Function Inclusive of Small Airways in Patients with uncontrolled Persistent Asthma: Results From a Phase 2b Clinical Trial
 - Effect of Dupilumab on FEV1 and Severe Exacerbation in Patients with Uncontrolled Persistent Asthma: A Subgroup Analysis Defined According to Early-Onset and Late-Onset Asthma

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

About Asthma

Asthma is a chronic inflammatory disease characterized by airway sensitivity to environmental and biologic factors. The response to these factors leads to an acute and chronic narrowing of the airways and increased mucus production. People with asthma can experience wheezing, shortness of breath, cough and chest tightness, and in severe cases, these symptoms can be life-threatening. Asthma prevalence continues to increase across all ages, genders and racial groups. Uncontrolled persistent asthma can have an impact on patients and their families, affecting their lives physically, functionally and psychologically.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Genzyme, the specialty care business unit of Sanofi, focuses on rare diseases, multiple sclerosis, oncology, and immunology. We help people with debilitating and complex conditions that are often difficult to diagnose and treat. Our approach is shaped by our experience developing highly specialized treatments and forging close relationships with physician and patient communities. We are dedicated to discovering and advancing new therapies, providing hope to patients and their families around the world. Learn more at www.sanofigenzyme.com.

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About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: <u>REGN</u>) is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for high LDL cholesterol, eye diseases, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including oncology, rheumatoid arthritis, asthma, atopic dermatitis, pain, and infectious diseases. For additional information about the company, please visit <u>www.regeneron.com</u> or follow @Regeneron on Twitter.

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2015. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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 dupilumab; 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 the clinical development programs evaluating dupilumab; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, such as dupilumab for uncontrolled persistent asthma or other indications; 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, such as dupilumab; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, 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 to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; 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 quidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC (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. 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, 2015 and its Form 10-Q for the quarterly period ended March 31, 2016. 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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