# REGENERON



#### **Press Release**

# Regeneron and Sanofi Announce Publication of Positive Phase 2 Dupilumab Data in the *Journal of the American Medical Association*

Study Evaluated Adult Patients with Chronic Sinusitis with Nasal Polyposis who did not Respond to Intranasal Corticosteroids

**Tarrytown, New York and Bridgewater, New Jersey** (February 2, 2016) – Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the *Journal of the American Medical Association* (JAMA) has published positive results from a Phase 2 study of dupilumab in adult patients with moderate-to-severe chronic sinusitis with nasal polyposis who did not respond to intranasal corticosteroids. Dupilumab is an investigational therapy that inhibits signaling of IL-4 and IL-13, two key cytokines required for the T helper 2 (Th2) immune response, which is believed to be a critical pathway in inflammation associated with chronic sinusitis with nasal polyps, asthma and atopic dermatitis. Dupilumab is currently under clinical development and its safety and efficacy have not been fully evaluated by any regulatory authority.

"Despite current treatment options, including surgery to remove polyps, some patients with chronic sinusitis with nasal polyposis continue to experience difficult symptoms, including nasal congestion, decreased or lost sense of smell, and facial pain, which can negatively impact their quality of life. In addition, patients with this condition may experience sleep disturbances and decreased productivity," said Claus Bachert, M.D., Ph.D., Professor and Head of Clinics, Department of Otorhinolaryngology, Ghent University Hospital, Ghent, Belgium and lead author of the JAMA paper. "This study, which also included patients with co-morbid asthma, supports previous observations that chronic sinusitis with nasal polyposis and asthma may share a core allergic inflammatory process driven by the IL-4 and IL-13 pathways."

The topline results of this study were <u>announced</u> in September 2014. Please refer to <u>today's</u> <u>online publication</u> for additional results from this study.

#### **About the Phase 2 Study**

The randomized, double-blind, placebo-controlled group study enrolled 60 adult patients with chronic sinusitis with nasal polyposis refractory to intranasal corticosteroids at 13 sites in the United States and Europe. Following four weeks of mometasone furoate nasal spray (MFNS) run-in, patients in the study received 300 milligrams (mg) of dupilumab or placebo once per week subcutaneously for 16 weeks, after an initial loading dose of 600 mg. All patients in the study continued to receive daily MFNS. Eligible patients had bilateral nasal polyposis and showed chronic symptoms of sinusitis, despite treatment with an intranasal corticosteroid for at least two months. Fifty-eight percent of patients in the study had received prior nasal surgery for their condition.

# **About Chronic Sinusitis with Nasal Polyposis**

Chronic sinusitis with nasal polyposis causes mucosal inflammation and polyps in the nasal cavity and sinuses<sup>i</sup>, which result in long-term symptoms of nasal obstruction and congestion, reduction in or loss of sense of smell, and facial pain.<sup>ii</sup> Nasal polyps can block normal drainage

from the sinuses<sup>iii</sup> and negatively impacts quality of life.<sup>iv</sup> Patients with nasal obstruction or congestion have a two-fold higher risk of sleep dysfunction,<sup>v</sup> increased fatigue<sup>vi</sup>, and decreased work productivity.<sup>vii</sup> About 75 percent of chronic sinusitis with nasal polyposis patients have a decreased sense of smell.<sup>viii</sup> The estimated prevalence of chronic sinusitis with nasal polyposis is up to 4 percent in the general population.<sup>ix</sup> Surgery may be considered in patients with chronic sinusitis with nasal polyposis who continue to experience nasal polyps and symptoms, despite medical treatment.<sup>ii</sup>

#### **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).

#### About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: REGN) 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 have 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 <a href="https://www.regeneron.com">www.regeneron.com</a> or follow <a href="https://www.regeneron.com">@ Regeneron</a> 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, 2014. 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 chronic sinusitis with nasal polyposis 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 reimbursement determinations third-party and by 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 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 and Bayer HealthCare LLC, 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, 2014 and its Form 10-Q for the quarter ended September 30, 2015. 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 quidance, 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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