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Regeneron and Sanofi Announce that Dupilumab Has Received FDA Breakthrough Therapy Designation in Atopic Dermatitis

TARRYTOWN, N.Y. and PARIS, Nov. 20, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to dupilumab for the treatment of adults with moderate-to-severe atopic dermatitis (AD) who are not adequately controlled with topical prescription therapy and/or for whom these treatments are not appropriate. Dupilumab is an investigational therapy blocking IL-4 and IL-13, two cytokines required for the Th2 immune response. The designation is based on positive results from Phase 1 and 2 clinical trials.

"Moderate-to-severe atopic dermatitis is a debilitating, life-altering disease with very limited treatment options. Many patients suffer for years with widespread inflamed skin, intense itch, sleep disturbances and other challenges," said Julie Block, Chief Executive Officer, National Eczema Association. "We are thrilled to see the FDA recognizing the need to expedite and prioritize potential new options for these patients."

Breakthrough Therapy designation was created by the FDA to expedite the development and review of drugs that target serious or life-threatening conditions. A Breakthrough Therapy drug must show preliminary clinical evidence of a substantial improvement on a clinically significant endpoint over available therapies, or over placebo if there is no available therapy. The designation includes all of the Fast Track program features, as well as more intensive FDA guidance and discussion. The Breakthrough Therapy designation is distinct from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met.

A Phase 3 worldwide clinical program for dupilumab in adults with moderate-to-severe atopic dermatitis is ongoing. For more information, please visit <http://clinicaltrials.gov>.

About Dupilumab and IL-4/IL-13 Signaling

Dupilumab, a fully-human monoclonal antibody, is directed against the shared IL-4 receptor alpha subunit, which blocks signaling from both IL-4 and IL-13. IL-4 and IL-13 are key cytokines that are required for the initiation and maintenance of the Th2 (Type 2 helper T-cell) immune response, which is believed to be a critical pathway in allergic inflammation.

Dupilumab was created using Regeneron's pioneering VelocImmune® technology and is being co-developed with Sanofi in atopic dermatitis, asthma and chronic sinusitis with nasal polyposis. Dupilumab is an investigational agent under clinical development and its safety and efficacy have not been fully evaluated by any regulatory authority.

About Atopic Dermatitis

Moderate-to-severe atopic dermatitis, a serious form of eczema, is a chronic inflammatory disease characterized by an allergic response driven by Type 2 helper T cells.

Moderate-to-severe forms of atopic dermatitis can be characterized by pronounced pruritus (itch), cutaneous dryness, and skin lesions marked by redness, infiltration/papulation, crusting/oozing, and lichenification (skin thickening), with periods of lesion exacerbation. Intense itching, scratching, and skin damage can lead to secondary infections. Atopic dermatitis is often associated with other inflammatory disorders such as asthma.^[1] Moderate-to-severe atopic dermatitis can negatively impact patients' lives and is associated with a high burden to society in terms of direct costs of medical care and prescription drugs and loss of productivity.^{[2]. [3]. [4]. [5]}

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new 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 eye diseases, colorectal cancer, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. Several Regeneron programs are based on human genetics findings. For additional information about the company, please visit www.regeneron.com.

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 policies 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, 2013. 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

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"), 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; unforeseen safety issues resulting from the administration of products and product candidates in patients, including without limitation dupilumab; serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials, such as the Phase 3 clinical program evaluating dupilumab in patients with moderate-to-severe atopic dermatitis; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, such as dupilumab, including the impact (if any) of the Breakthrough Therapy designation to dupilumab for the treatment of adults with moderate-to-severe atopic dermatitis that is not adequately controlled with topical prescription therapy and/or for whom these treatments are not appropriate; ongoing regulatory obligations and oversight impacting Regeneron's 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; 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 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, 2013 and its Form 10-Q for the quarter ended September 30, 2014. 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.

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