



## Regeneron and Sanofi Announce Publication of Positive Phase 2b Dupilumab Data in The Lancet

October 8, 2015

Regeneron and Sanofi Announce Publication of Positive Phase 2b Dupilumab Data in The Lancet

TARRYTOWN, N.Y. and Paris, October 8, 2015 - Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi (EURONEXT: **SAN** and NYSE: **SNY**) today announced the publication in *The Lancet* of results from a Phase 2b 16-week, dose-ranging study of dupilumab, an investigational therapy, in 380 adult patients with moderate-to-severe atopic dermatitis who were not adequately controlled on topical 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.

"Moderate-to-severe atopic dermatitis is a chronic disease with limited treatment options and is associated with debilitating itching, widespread rash, sleep disturbance and other issues," said Diamant Thaçi, M.D., Professor, University Hospital Schleswig-Holstein, Campus Lübeck, Lübeck, Germany and lead author of The Lancet paper. "Observations in this study suggest that selective inhibition of the IL-4 and IL-13 cytokines with investigational monoclonal antibody dupilumab may improve severity and symptoms of this difficult-to-treat disease."

The topline results of this study were [announced](#) in July 2014. Please refer to [today's online publication](#) for additional results from this study.

Results from Phase 3 studies of dupilumab for the treatment of adults with moderate-to-severe atopic dermatitis that is not adequately controlled with topical atopic dermatitis medications are expected in the first half of 2016. Dupilumab is currently under clinical development and its safety and efficacy have not been fully evaluated by any regulatory authority.

### About Atopic Dermatitis

Atopic dermatitis - a serious form of eczema - is a chronic inflammatory disorder characterized by itchy, inflamed skin that can be present on any part of the body.<sup>1,2</sup> Though symptoms appear externally, atopic dermatitis is fueled by underlying activation of the immune system.<sup>3</sup> Atopic dermatitis affects approximately 5-7 million adults in the U.S.<sup>4,5</sup> and it is estimated that 20 percent experience moderate-to-severe disease.<sup>6</sup> Worldwide, 1 to 3 percent of adults are impacted.<sup>7</sup> Though symptoms may vary, moderate-to-severe disease can be burdensome to patients, often characterized by pruritus (itch), cutaneous dryness, and skin lesions marked by redness, crusting/oozing and lichenification (skin thickening) with periods of lesion exacerbation.<sup>8,9,10</sup> Intense itching, scratching and skin damage can lead to secondary infections, as well as anxiety, depression, and feelings of social isolation.<sup>11,12,13,14,15</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 [www.regeneron.com](http://www.regeneron.com) 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 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, 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 and possible liability resulting from the administration of products and product candidates (including without limitation dupilumab) in patients; serious complications or side effects in connection with the use of Regeneron's products and product candidates in clinical trials, such as the Phase 3 studies of dupilumab for the treatment of adults with moderate-to-severe atopic dermatitis that is not adequately controlled with topical atopic dermatitis medications; 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; 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, including without limitation dupilumab; 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 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 quarterly period ended June 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 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>).

#### **Contacts Sanofi:**

##### **Media Relations**

**Jack Cox**

Tel: +33 (0) 1 53 77 94 74

[jack.Cox@sanofi.com](mailto:jack.Cox@sanofi.com)

##### **Investor Relations**

**Sebasti  n Martel, Ph.D.**

Tel: +33 (0)1 53 77 45 45

[ir@sanofi.com](mailto:ir@sanofi.com)

#### **Contacts Regeneron:**

##### **Media Relations**

**Ilana Tabak**

Tel: + 1 (914) 847-3836

[ilana.tabak@regeneron.com](mailto:ilana.tabak@regeneron.com)

##### **Investor Relations**

**Manisha Narasimhan, Ph.D.**

Tel: +1 (914) 847-5126

[Manisha.narasimhan@regeneron.com](mailto:Manisha.narasimhan@regeneron.com)

<sup>1</sup> World Allergy Association 2004: [http://www.worldallergy.org/professional/allergic\\_diseases\\_center/atopiceczema/](http://www.worldallergy.org/professional/allergic_diseases_center/atopiceczema/). Accessed September 2, 2015.

<sup>2</sup> Bieber T. Mechanisms of disease: atopic dermatitis. N Engl J Med 2008;358:1483-9

<sup>3</sup> Leung DYM, Boguniewicz M, Howell MD, Nomura I, Hamid QA. New insights into atopic dermatitis. J Clin Invest. 2004;113:651-657.

<sup>4</sup> Eichenfield LF, Tom WL, Chamlin SL, et al. Guidelines of care for the management of atopic dermatitis. Section 1. J Am Acad Dermatol. 2014;70:338-51.

<sup>5</sup> United States Census. 2013 population estimates for US atopic dermatitis: adults ages 18 and older (242,542,967). Note: prevalence figures given in text are rounded from multiplying the adult population by the 2% - 3% prevalence figures in Reference 4.

<sup>6</sup> Hamilton, Jennifer D. et al. 2014. Dupilumab improves the molecular signature in skin of patients with moderate-to-severe atopic dermatitis. Journal of Allergy and Clinical Immunology, Volume 134, Issue 6 , 1293 - 1300.

<sup>7</sup> Nutten S. Atopic Dermatitis: Global Epidemiology and Risk Factors. Ann Nutr Metab 2015;66(suppl 1):8-16.

<sup>8</sup> NIH 2014: [http://www.niams.nih.gov/health\\_info/atopic\\_dermatitis/atopic\\_dermatitis\\_ff.asp](http://www.niams.nih.gov/health_info/atopic_dermatitis/atopic_dermatitis_ff.asp). Accessed August 11, 2015.

<sup>9</sup> Misery L, Finlay AY, Martin N, et al. Atopic dermatitis: impact on the quality of life of patients and their partners. Dermatology. 2007;215:123-129.

<sup>10</sup> Zuberbier T, Orlow SJ, Pallier AS, et al. Patient perspectives on the management of atopic dermatitis. J Allergy Clin Immunol. 2006;118:226-232.

- <sup>11</sup> Simpson EL. Comorbidity in atopic dermatitis. *Curr Dermatol Rep.* 2012;1:29-38.
- <sup>12</sup> Gupta MA, Gupta AK. Depression and suicidal ideation in dermatology patients with acne, alopecia areata, atopic dermatitis and psoriasis. *Br J Dermatol.* 1998;139:846-850
- <sup>13</sup> Kimata H. Prevalence of suicidal ideation in patients with atopic dermatitis. *Suicide Life Threat Behav.* 2006;36:120-124.
- <sup>14</sup> Yarbrough KB, Neuhaus KJ, Simpson EL. The effects of treatment on itch in atopic dermatitis. *Dermatol Ther.* 2013;26:110-119.