



## Regeneron and Sanofi Receive Positive CHMP Opinion for Dupixent® (dupilumab) to Treat Adult Patients with Moderate-to-Severe Atopic Dermatitis

July 21, 2017

TARRYTOWN, N.Y. and PARIS, July 21, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today announced that the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for the marketing authorization of Dupixent® (dupilumab), recommending its approval in Europe for use in adults with moderate-to-severe atopic dermatitis (AD) who are candidates for systemic therapy.

AD, a form of eczema, is a chronic inflammatory disease with symptoms often appearing as a rash on the skin.<sup>1,2,3,4</sup> Moderate-to-severe AD is characterized by rashes often covering much of the body, and can include intense, persistent itching and skin dryness, cracking, redness, crusting, and oozing.<sup>5</sup> Itch is one of the most burdensome symptoms for patients and can be debilitating. In addition, people with moderate-to-severe AD experience a high level of disrupted sleep, and increased anxiety and depression symptoms due to their disease.<sup>6</sup>

Dupixent is a human monoclonal antibody that is designed to specifically inhibit overactive signaling of two key proteins, IL-4 and IL-13, which are believed to be major drivers of the persistent underlying inflammation in AD. If approved, Dupixent will come in a pre-filled syringe for self-administration by a patient as a subcutaneous injection every other week after an initial loading dose.<sup>7</sup> Dupixent can be used with or without topical corticosteroids.

The European Commission (EC) is expected to make a final decision on the Marketing Authorization Application (MAA) for Dupixent in the European Union in the coming months. The CHMP opinion is based on studies from the global LIBERTY AD clinical trial program, including SOLO 1, SOLO 2, SOLO-CONTINUE, CHRONOS and CAFÉ. These studies incorporated data from nearly 3,000 adult patients with moderate-to-severe AD not adequately controlled with topical prescription therapies or immunosuppressants such as cyclosporine, or when those therapies were not advisable.

In the US, Dupixent is approved for the treatment of adults with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.<sup>8</sup>

### IMPORTANT SAFETY INFORMATION for U.S.

**Do not use** if you are allergic to dupilumab or to any of the ingredients in Dupixent®.

**Before using Dupixent, tell your healthcare provider about all your medical conditions, including if you:**

- have eye problems
- have a parasitic (helminth) infection
- have asthma
- are scheduled to receive any vaccinations. You should not receive a "live vaccine" if you are treated with Dupixent.
- are pregnant or plan to become pregnant. It is not known whether Dupixent will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known whether Dupixent passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. If you have asthma and are taking asthma medicines, do not change or stop your asthma medicine without talking to your healthcare provider.

**Dupixent can cause serious side effects, including:**

- **Allergic reactions.** Stop using Dupixent and go to the nearest hospital emergency room if you get any of the following symptoms: fever, general ill feeling, swollen lymph nodes, hives, itching, joint pain, or skin rash.
- **Eye problems.** Tell your healthcare provider if you have any new or worsening eye problems, including eye pain or changes in vision.

**The most common side effects include** injection site reactions, eye and eyelid inflammation, including redness, swelling and itching, and cold sores in your mouth or on your lips.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Dupixent. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Use Dupixent exactly as prescribed. If your healthcare provider decides that you or a caregiver can give Dupixent injections, you or your caregiver should receive training on the right way to prepare and inject Dupixent. **Do not** try to inject Dupixent until you have been shown the right way by your healthcare provider.

Please click [here](#) for the full Prescribing Information. The patient information is available [here](#).

## About Regeneron Pharmaceuticals, Inc.

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 consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates, 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 its proprietary *VelociSuite*<sup>®</sup> technologies, including *VelocImmune*<sup>®</sup> which yields 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](http://www.regeneron.com) or follow @Regeneron on Twitter.

## About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi is organized into five global business units: Diabetes and Cardiovascular, General Medicines and Emerging Markets, Sanofi Genzyme, Sanofi Pasteur and Consumer Healthcare. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Genzyme focuses on developing specialty treatments for debilitating diseases that are often difficult to diagnose and treat, providing hope to patients and their families.

## 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<sup>®</sup> (dupilumab); the impact of the opinion adopted by the European Medicine Agency's Committee for Medicinal Products for Human Use discussed in this news release on the European Commission's decision regarding the Marketing Authorization Application for Dupixent for use in adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, such as Dupixent (including possible regulatory approval of Dupixent in the European Union discussed in this news release and possible regulatory approval of Dupixent in other jurisdictions and indications); unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients, including without limitation Dupixent; serious complications or side effects in connection with the use of Regeneron's products and product candidates (such as Dupixent) in clinical trials; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management companies; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies; 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 Dupixent; 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; 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, 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 relating to Praluent<sup>®</sup> (alirocumab) Injection, the permanent injunction granted by the United States District Court for the District of Delaware that, if upheld on appeal, would prohibit Regeneron and Sanofi from marketing, selling, or manufacturing Praluent in the United States, the outcome of any appeals regarding such injunction, the ultimate outcome of such litigation, 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 March 31, 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>).

## 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 regarding the clinical development of and potential marketing approvals for the product. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans", "will be" 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 of the product, 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 the product as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of the product, the absence of guarantee that the product if approved will be commercially successful, risks associated with intellectual property, future litigation, the future approval and commercial success of therapeutic alternatives, and volatile economic conditions, as well as those risks 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, 2016. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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**References**

<sup>1</sup> Schneider et al, AAAI 2013, Practice Parameter Update, page 296

<sup>2</sup> Eichenfield et al, AAD 2014, Guidelines of Care for Atopic Dermatitis, page 118

<sup>3</sup> Guideline to treatment, European Dermatology Forum. <http://www.euroderm.org/edf/index.php/edf-guidelines/category/5-guidelines-miscellaneous?download=36:guideline-treatment-of-atopic-eczema-atopic-dermatitis>. Accessed December 23, 2016

<sup>4</sup> Gelmetti and Wolleberg, BJD 2014, Atopic dermatitis- all you can do from the outside. Page 19

<sup>5</sup> National Institutes of Health (NIH). Handout on Health: Atopic Dermatitis (A type of eczema) 2013. [http://www.niams.nih.gov/Health\\_Info/Atopic\\_Dermatitis/default.asp](http://www.niams.nih.gov/Health_Info/Atopic_Dermatitis/default.asp). Accessed October 31, 2016.

<sup>6</sup> Simpson, E, Bieber, T and Eckert, L, "Patient burden of moderate to severe atopic dermatitis (AD): Insights from a phase 2b clinical trial of dupilumab in adults," Am Acad Dermatol, pp. 74(3):491-498, 2016.

<sup>7</sup> Dupixent Summary of Product Characteristics.

<sup>8</sup> Dupixent Prescribing Information 2017. [https://www.regeneron.com/sites/default/files/Dupixent\\_FPI.pdf](https://www.regeneron.com/sites/default/files/Dupixent_FPI.pdf). Accessed July 2017.

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