



Regeneron Announces Approval of DUPIXENT® (dupilumab) in Japan for the Treatment of Atopic Dermatitis

January 22, 2018

TARRYTOWN, N.Y., Jan. 22, 2018 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that the Ministry of Health, Labor and Welfare (MHLW) in Japan has granted marketing and manufacturing authorization for DUPIXENT® (dupilumab) for the treatment of atopic dermatitis in adults not adequately controlled with existing therapies. Dupixent is being jointly developed by Regeneron and Sanofi under a global collaboration agreement, and will be commercialized in Japan by Sanofi.

Atopic dermatitis (AD), a form of eczema, is a chronic inflammatory disease with symptoms often appearing as a rash on the skin. Moderate-to-severe atopic dermatitis is characterized by rashes sometimes covering much of the body, and can include intense, persistent itching and skin dryness, cracking, redness, crusting and oozing. Itch is one of the most burdensome symptoms for patients and can be debilitating.

DUPIXENT is a human monoclonal antibody designed to specifically inhibit signaling of two key proteins, IL-4 and IL-13, which are believed to be important contributors of the persistent underlying inflammation in atopic dermatitis, and certain other allergic or atopic diseases. DUPIXENT will come in a 300mg pre-filled syringe and be delivered as a subcutaneous injection every other week after an initial loading dose. DUPIXENT can be used with or without topical corticosteroids.

In March 2017, the U.S. Food & Drug Administration (FDA) approved DUPIXENT in the U.S. for the treatment of adults with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. The European Commission (EC) also granted marketing authorization for DUPIXENT for use in adults with moderate-to-severe atopic dermatitis who are candidates for systemic therapy in September 2017.

Dupilumab Program Overview

Dupilumab is currently being evaluated in a comprehensive development program for AD that includes studies in children with severe AD (6 months to 11 years of age) and adolescents with moderate-to-severe AD (12 to 17 years of age). Dupilumab is also being studied in other Type 2 inflammatory diseases that are believed to be driven by the IL-4/IL-13 pathway, including uncontrolled moderate-to-severe asthma for which a supplemental biologics license application has been submitted to the FDA for patients aged 12 and over, as well as nasal polyposis (Phase 3) and eosinophilic esophagitis (Phase 2). These potential uses are investigational and the safety and efficacy have not been fully evaluated by any regulatory authority. Dupilumab was discovered using Regeneron's proprietary *VelocImmune*® technology that yields optimized fully-human antibodies, and is being jointly developed by Regeneron and Sanofi under a global collaboration agreement.

IMPORTANT SAFETY INFORMATION

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 by physician-scientists for the past 30 years, our unique ability to repeatedly and 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*® technologies, including *VelocImmune*® to yield 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 or follow @Regeneron on Twitter.

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® (dupilumab) Injection; 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, such as dupilumab for the treatment of pediatric atopic dermatitis, uncontrolled moderate-to-severe asthma, nasal polyposis, eosinophilic esophagitis, and other potential indications; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in later studies and lead to therapeutic applications; unforeseen safety issues and possible liability 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 products and product candidates (such as dupilumab) 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 proceedings relating to Praluent® (alirocumab) Injection, the ultimate outcome of any such litigation proceedings, 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 September 30, 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>).

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