Regeneron and Sanofi Announce Approval of DUPIXENT® (dupilumab) to Treat Adult Patients with Moderate-to-Severe Atopic Dermatitis in the European Union

September 28, 2017

TARRYTOWN, N.Y. and PARIS, Sept. 28, 2017 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced that the European Commission (EC) has granted marketing authorization for DUPIXENT® (dupilumab), for use in adults with moderate-to-severe atopic dermatitis (AD) who are candidates for systemic therapy.

Atopic dermatitis, 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 often 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. In addition, people with moderate-to-severe atopic dermatitis experience impaired quality of life, including disrupted sleep, and increased anxiety and depression symptoms along with their disease.

"People with moderate-to-severe atopic dermatitis can experience unbearable symptoms that may significantly impact their quality of life. Many often struggle to control their disease with the treatment options currently available," said Christine Janus, Chief Executive Officer of the International Alliance of Dermatology Patient Organizations. "We support timely access to this important new medication for those with moderate-to-severe atopic dermatitis to help them control and provide relief for this life-altering, often severely debilitating, chronic disease."

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 atopic dermatitis, and certain other allergic or atopic diseases. DUPIXENT will come in a pre-filled syringe and can be self-administered by a patient as a subcutaneous injection every other week after an initial loading dose. DUPIXENT can be used with or without topical corticosteroids.

"This approval of DUPIXENT in Europe demonstrates our approach of bringing innovative new therapies to those living with the highest unmet medical need and today's approval represents an important milestone for people living with moderate-to-severe atopic dermatitis in Europe," said Elias Zerhouni, M.D., President, Global R&D, Sanofi. "DUPIXENT targets an underlying cause of atopic dermatitis, helps clear the skin, manage the persistent debilitating itch, and improve overall quality of life. We are now focused on quickly making this important new treatment option available to people across Europe who live with this systemic disease."

Following the granting of this marketing authorization, Sanofi and Regeneron will work with relevant local authorities to make DUPIXENT available to patients in need in countries across Europe.

"DUPIXENT represents the culmination of decades of our scientific research into the biology of allergic diseases such as moderate-to-severe atopic dermatitis," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer, Regeneron. "We continue to evaluate the potential of dupilumab in the treatment of atopic dermatitis in children and adolescents as well as other allergic inflammatory diseases driven by the IL-4/IL-13 pathway."

DUPIXENT is approved in the U.S. for the treatment of adults with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. DUPIXENT can be used with or without topical corticosteroids. It is not known if DUPIXENT is safe and effective in children.

LIBERTY AD Clinical Program and Results
The approval of DUPIXENT was based on studies from the global LIBERTY AD clinical trial program which included nearly 3,000 patients. LIBERTY AD studies included SOLO 1, SOLO 2, CHRONOS, SOLO-CONTINUE and CAFÉ. The studies examined the use of DUPIXENT either alone (SOLO 1, SOLO 2 and SOLO-CONTINUE) or with topical corticosteroids (CHRONOS or CAFÉ) in moderate-to-severe AD patients who were inadequately controlled with topical prescription therapies or immunosuppresants such as cyclosporine, or for whom those therapies were not advisable. In all these studies, DUPIXENT alone or with topical corticosteroids met the primary and key secondary endpoints. The most common adverse events that occurred at a higher rate than placebo in the DUPIXENT group (&#62 one percent) included injection site reactions, eye and eye lid inflammation including redness, swelling, and itching, and cold sores in the mouth or on the lips.

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). These potential uses are investigational and the safety and efficacy have not been fully evaluated nor confirmed by any regulatory authority.

Dupilumab is also being studied in other inflammatory diseases that are believed to be driven by the IL-4/IL-13 pathway, including uncontrolled persistent asthma (Phase 3), 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 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 repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and over a dozen product candidates in development, 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, and infectious and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through its unique *VelociSuite*® technologies 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.

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® (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 Dupixent for the treatment of uncontrolled moderate-to-severe atopic dermatitis in other potential jurisdictions, as well as 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 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® (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 June 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).

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 marketing and other potential of the product, or regarding potential future revenues from the product. 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, unexpected regulatory actions or delays, or government regulation generally, that could affect the availability or commercial potential of the product, the absence of guarantee that the product will be commercially successful, the uncertainties inherent in research and development, including future clinical data and analysis of existing clinical data relating to the product, including post marketing, unexpected safety, quality or manufacturing issues, competition in general, risks associated with intellectual property and any related litigation and the ultimate outcome of such litigation, 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.

Contacts Regeneron:

Media Relations	**Investor Relations**
Arleen Goldenberg	**Manisha Narasimhan, Ph.D.**
Tel: + 1 (914) 847-3456	Tel: +1 (914) 847-5126
Mobile: +1 (914) 260-8788	Manisha.narasimhan@regeneron.com
Arleen.Goldenberg@regeneron.com	

Contacts Sanofi:

Media Relations	**Investor Relations**
Ashleigh Koss	**George Grofik**
Tel: 908-981-8745	Tel: +33 (0) 1 53 77 94 69
ashleigh.koss@sanofi.com	ir@sanofi.com