Positive Phase 3 Results Presented for Dupixent® (dupilumab) Show Significant Improvement on Multiple Measures of Disease Severity in Adolescents with Moderate-to-Severe Atopic Dermatitis

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Results on skin clearing, itch and certain quality of life measurements were presented today as a late-breaking oral presentation at the 27th EADV Congress

Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Sanofi today presented detailed results from a pivotal Phase 3 trial showing Dupixent® (dupilumab) monotherapy demonstrated a significant improvement in signs and symptoms of atopic dermatitis and certain quality of life measures in adolescent patients (12-17 years) with moderate-to-severe atopic dermatitis, whose disease was inadequately controlled with topical therapies or for whom topical treatment was medically inadvisable. These data were presented at the 27th European Academy of Dermatology and Venereology (EADV) Congress in Paris, France.

There continues to be a significant unmet need for adolescents with moderate-to-severe atopic dermatitis, whose disease cannot be controlled with topical treatments. There are no systemic biologic medications approved for this patient population. Dupixent is currently approved for use in certain adult patients with moderate-to-severe atopic dermatitis in countries including the U.S., European Union, Canada and Japan. The results from this trial in adolescents form the basis of regulatory submissions for patients ages 12 to 17.

"Limited treatment options leave adolescents with uncontrolled moderate-to-severe atopic dermatitis to cope with intense, unrelenting itch and skin lesions," said Amy S. Paller, M.D., Director of the Northwestern University Skin Disease Research Center and principal investigator of the trial. "The results we are presenting today show the potential for Dupixent in adolescents to not only help clear the skin and reduce itching, but also improve certain aspects of quality of life in adolescents who may be dealing with these unbearable symptoms."

The late-breaking presentation at EADV included the following data:

The co-primary endpoint outside of the U.S. was 75% improvement in Eczema Area and Severity Index (EASI-75) at 16 weeks. In the U.S., the primary endpoint was the proportion of patients achieving Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear):

- 41.5% of patients who received Dupixent every two weeks and 38% of patients who received Dupixent every four weeks achieved 75% or greater skin improvement (EASI-75) compared to 8% with placebo (p less than 0.001).
- 24% of patients who received weight-based dosing of Dupixent every two weeks (200 mg or 300 mg) and 18% of patients who received a fixed dose of Dupixent every four weeks (300 mg) achieved the primary endpoint – clear or almost-clear skin (IGA; score of 0 or 1) – compared with 2% with placebo (p less than 0.001).

With regard to key secondary endpoints at 16 weeks:

- There was a 66% improvement in the Dupixent every two weeks group and 65% improvement in the Dupixent every four weeks group in average percent change from baseline in EASI score compared with a 24% improvement in the placebo group (p less than 0.001).
- There was a 48% improvement in the Dupixent every two weeks group and 45.5% improvement in the Dupixent every four weeks group in average percent change from baseline in the pruritus numerical rating scale (NRS) compared with a 19% improvement in the placebo group (p less than 0.001).
- 49% of patients who received Dupixent every two weeks and 39% of patients who received Dupixent every four weeks achieved at least a 3-point improvement on the peak pruritus numerical rating scale (pp-NRS) compared to 9% with placebo (p less than 0.001). At the beginning of the trial, patients reported a mean itch score of 7.6 on the 10-point pp-NRS scale.

Also at 16 weeks, additional secondary endpoints were:

- The majority of patients who received Dupixent (61% of patients treated every two weeks and 55% of patients treated every four weeks) achieved at least a 50% improvement in EASI (EASI-50) compared to 13% with placebo (p less than 0.001).
- There was a 52% improvement in the Dupixent every two weeks group and 47.5% improvement in the Dupixent every four weeks group compared to an 18% improvement in the placebo group in mean percent change from baseline in SCORing Atopic Dermatitis (SCORAD), a combined measure of area and severity of atopic dermatitis on the skin as well as patient-reported symptoms of itch and sleeplessness (p less than 0.001).
- Patients who received Dupixent every two weeks or every four weeks significantly improved quality of life measured by the Children's Dermatology Life Quality Index (CDLQI) and patient-reported symptoms measured by the Patient-Oriented

Eczema Measure (POEM) compared with placebo (p less than 0.001).

Additionally in the 16-week trial, 59% of patients on placebo used rescue medications compared with 21% of patients receiving Dupixent every two weeks and 32.5% of patients receiving Dupixent every four weeks.

The overall rate of adverse events was 72% for Dupixent every two weeks, 64% for Dupixent every four weeks and 69% for placebo.

Adverse events that were observed more frequently with Dupixent included injection site reactions (8.5% for Dupixent every two weeks, 6% for Dupixent every four weeks compared with 3.5% for placebo) and conjunctivitis (10% for Dupixent every two weeks, 11% for Dupixent every four weeks compared with 5% for placebo). Skin infections were numerically lower in the Dupixent groups (11% for Dupixent every two weeks, 13% for Dupixent every four weeks compared with 20% for placebo).

The safety and efficacy of Dupixent in the adolescent atopic dermatitis population have not been fully evaluated by any regulatory authority.

About the Dupixent Trial in Adolescent Patients
The pivotal, Phase 3 trial evaluating the efficacy and safety of Dupixent monotherapy in adolescent patients with moderate-to-severe atopic dermatitis is the first Phase 3 trial of a biologic in this patient population. The trial enrolled 251 patients who were 12 years to 17 years of age with moderate-to-severe atopic dermatitis whose disease could not be adequately controlled with topical medications or for whom topical treatment was medically inadvisable.

Patients were randomized into one of three treatment groups for the controlled period of 16 weeks: the first group was treated with Dupixent subcutaneous injection 200 mg or 300 mg every two weeks, based on weight (with an initial dose of 400 mg or 600 mg respectively). The second group was treated with 300 mg Dupixent every four weeks (with an initial dose of 600 mg), and the third group was treated with placebo every two weeks. No topical corticosteroids were permitted unless a patient had a severe flare and required rescue medication.

The co-primary endpoints outside of the U.S. and a key secondary endpoint in the U.S. was the proportion of patients who achieved 75% or greater skin improvement as measured by the EASI-75 at Week 16. EASI is a validated scale used to measure the extent and severity of the disease. In the U.S., the primary endpoint of this trial was the proportion of patients with an IGA score of 0 or 1 at Week 16. The IGA is a 5-point scale ranging from 0 (clear) to 4 (severe) that measures overall severity of skin lesions.

In the trial, 92% of patients had at least one other atopic or allergic condition, including 66% with allergic rhinitis, 61% with food allergy, 54% with asthma, 29% with hives and 23% with allergic conjunctivitis.

About Moderate-to-Severe Atopic Dermatitis
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 that can potentially cover much of the body, and can include intense, persistent itching, skin lesions and skin dryness, cracking, redness, crusting and oozing. Itch is one of the most burdensome symptoms for patients and can be debilitating.

About Dupixent® (dupilumab)
Dupixent works by inhibiting interleukin-4 and interleukin-13 (IL-4 and IL-13), which are important contributors to Type 2 inflammation, a systemic, allergic response known to play a role in moderate-to-severe atopic dermatitis.

In 2016, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for Dupixent for the treatment of moderate-to-severe (12 to 17 years of age) and severe (6 months to 11 years of age) atopic dermatitis not well controlled on topical prescription medications.

Dupixent is currently approved in the U.S. as a treatment for adults with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent is approved in the European Union for use in adults with moderate-to-severe atopic dermatitis (AD) who are candidates for systemic therapy. Dupixent is also approved for certain patients with moderate-to-severe atopic dermatitis in a number of other countries, including Canada and Japan. More than 50,000 adult patients with atopic dermatitis have been prescribed Dupixent to date.

About Type 2 Inflammation in Atopic Dermatitis
Through scientific advances in immune based disease biology, we now understand that a particular type of inflammation, called Type 2 inflammation, contributes to the cause of atopic dermatitis. The immune system includes different immune cells and signaling proteins, including interleukins. Interleukin-4 (IL-4) and interleukin-13 (IL-13) are central drivers of Type 2 allergic inflammation in atopic dermatitis, as well as a range of other allergic or atopic diseases.

Dupilumab Development Program
Regeneron and Sanofi are also studying dupilumab in a broad range of clinical development programs for diseases driven by Type 2 inflammation, including asthma (Phase 3), pediatric (6-11 years) atopic dermatitis (Phase 3), nasal polyps (Phase 3), eosinophilic esophagitis (Phase 3) and grass allergy (Phase 2). Future trials are planned for chronic obstructive pulmonary disease and food allergy (including peanut). These potential uses are investigational and the safety and efficacy have not been 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 AND INDICATION
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.

INDICATION
Dupixent is used to treat adult patients 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.

About Regeneron
Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and numerous product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neuromuscular diseases, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*® technologies, such as *VelocImmune*® which produces optimized fully-human antibodies, and ambitious research initiatives such as the Regeneron Genetics Center, which is conducting 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 is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

Regeneron Forward-Looking Statements and Use of Digital Media
This press 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 moderate-to-severe atopic dermatitis in adolescents, pediatric atopic dermatitis, asthma, nasal polyps, eosinophilic esophagitis, grass allergy, chronic obstructive pulmonary disease, food allergy (including peanut), and other potential indications; unforeseen safety issues resulting from the administration of products and product candidates (such as dupilumab) in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting Regeneron's marketed products (such as Dupixent), 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, 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; the ability of

Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product candidates; the availability and extent of reimbursement of the Company's products (such as Dupixent) from third-party payers, including private payer healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payers and new policies and procedures adopted by such payers; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its 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 EYLEA® (aflibercept) Injection, Dupixent, and 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 U.S. Securities and Exchange Commission, including its Form 10-Q for the quarterly period ended June 30, 2018. 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 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 affectthe 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, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic conditions, the impact of cost containment initiatives and subsequent changes thereto, 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, 2017. 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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