Press Release

**FDA accepts Dupixent® (dupilumab) for priority review in adults with prurigo nodularis**

- Dupixent would be the first and only medicine specifically indicated to treat prurigo nodularis in the U.S., if approved
- Acceptance marks another important step in advancing Dupixent for a broad range of diseases with underlying type 2 inflammation

**Paris and Tarrytown, N.Y. May 31, 2022.** The U.S. Food and Drug Administration (FDA) has accepted for priority review the supplemental Biologics License Application (sBLA) for Dupixent® (dupilumab) to treat adults with prurigo nodularis, a chronic inflammatory skin disease that causes extreme itch and skin lesions. The target action date for the FDA decision is September 30, 2022.

The sBLA is supported by data from two pivotal Phase 3 trials evaluating the efficacy and safety of Dupixent in patients 18 years and older with uncontrolled prurigo nodularis (PRIME2 and PRIME). Both trials met the primary and key secondary endpoints, showing Dupixent significantly improved disease signs and symptoms compared to placebo, including reduction in itch and skin lesions. The safety results from these trials were generally consistent with the known safety profile of Dupixent in atopic dermatitis. The adverse event more commonly observed with Dupixent was conjunctivitis.

The FDA grants priority review to therapies that have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions. Additional regulatory filings outside of the US are also planned in 2022. The potential use of Dupixent in prurigo nodularis is currently under clinical development, and the safety and efficacy have not been fully evaluated by any regulatory authority.

**About Prurigo Nodularis**

People with prurigo nodularis experience intense, persistent itch, with thick skin lesions (called nodules) that can cover most of the body. Prurigo nodularis is often described as painful with burning, stinging and tingling of the skin. The impact of uncontrolled prurigo nodularis on quality of life is one of the highest among inflammatory skin diseases due to the extreme itch and is comparable to other debilitating chronic diseases that can negatively affect mental health, activities of daily living and social interactions. High-potency topical steroids are commonly prescribed but are associated with safety risks if used long term. There are approximately 75,000 people in the U.S. who are unable to control their disease with systemic therapy and are most in need of a treatment option.

**About Dupixent**

Dupixent is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL-4) and interleukin-13 (IL-13) pathways and is not an immunosuppressant. The Dupixent development program has shown significant clinical benefit and a decrease in type 2 inflammation in Phase 3 trials, establishing that IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases. These diseases include approved indications for Dupixent such as asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis and eosinophilic esophagitis, as well as investigational diseases such as prurigo nodularis.

Dupixent is approved for use in certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis and eosinophilic esophagitis in different age populations in a
number of countries around the world. Dupixent is currently approved across these indications in the U.S. and for one or more of these indications in the European Union, Japan and more than 60 countries. More than 400,000 patients have been treated with Dupixent globally.

**Dupilumab Development Program**

Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement. To date, dupilumab has been studied in more than 60 clinical trials involving more than 10,000 patients with various chronic diseases driven in part by type 2 inflammation.

In addition to the currently approved indications, Sanofi and Regeneron are studying dupilumab in a broad range of diseases driven by type 2 inflammation or other allergic processes in Phase 3 trials, including prurigo nodularis, pediatric eosinophilic esophagitis, hand and foot atopic dermatitis, chronic inducible urticaria-cold, chronic spontaneous urticaria, chronic pruritis of unknown origin, chronic obstructive pulmonary disease with evidence of type 2 inflammation, chronic rhinosinusitis without nasal polyposis, allergic fungal rhinosinusitis, allergic bronchopulmonary aspergillosis and bullous pemphigoid. These potential uses of dupilumab are currently under clinical investigation, and the safety and efficacy in these conditions have not been fully evaluated by any regulatory authority.

**About Regeneron**

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to nine FDA-approved treatments and numerous product candidates in development, almost 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, pain, hematologic conditions, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary **VelociSuite** technologies, such as **VelocImmune**, which uses unique genetically humanized mice to produce optimized fully human antibodies and bispecific antibodies, and through 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](http://www.regeneron.com) or follow @Regeneron on Twitter.

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**About Sanofi**

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people’s lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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**Regeneron Media Relations**
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 and the product candidates, the uncertainty inherent in research and development programs, including clinical trials, the uncertainty of patent applications and/or decisions, the possibility of successful development and/or commercialization, the uncertainties inherent in research and development programs conducted by Sanofi and/or its collaborators or licensees (collectively, “Sanofi’s Products”), and the global economy; the nature, timing, and scope of possible regulatory actions and approvals for Sanofi’s Products and Sanofi’s Product Candidates; the extent and nature of customer acceptance and demand for Sanofi’s Products and Sanofi’s Product Candidates; determinations by regulatory and administrative governmental authorities which may delay or prevent approval of or commercial launch of Sanofi’s Products and Sanofi’s Product Candidates; unanticipated expenses, including those identified 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, 2021. 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 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 those 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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron’s business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, the ability of Regeneron’s collaborators or licensees to manage their supply chain, the ability of Regeneron and its collaborators to conduct research and development programs, Regeneron’s ability to manage its supply chain, and to conduct research and clinical programs, Regeneron’s ability to manage its supply chain, the ability of Regeneron’s collaborators or licensees to manage their supply chain, and the ability of Regeneron and its collaborators to conduct research and clinical programs, including Regeneron’s ability to conduct research and clinical programs, the ability of Regeneron’s collaborators or licensees to conduct research and clinical programs, and the ability of Regeneron and its collaborators to conduct research and clinical programs, and the impact any of the foregoing may have on Regeneron’s business, prospects, operating results, and financial condition. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Regeneron including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Regeneron’s annual report on Form 10-K for the year ended December 31, 2021. Other than as required by applicable law, Regeneron does not undertake any obligation to update or revise any forward-looking statements.

Regeneron is a leading biotechnology company that invents, develops and commercializes medicines for the treatment of serious medical conditions. Regeneron’s medicines are also used as research tools to accelerate scientific discovery and drug development. Regeneron’s medicines and pipeline include treatments for eye diseases, inflammatory diseases, autoimmune diseases, cardiovascular and metabolic diseases, oncology, hematologic diseases, infectious diseases, pain and rare diseases. Additional information about Regeneron is available at www.regeneron.com.
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).