

Sanofi to present growth opportunities and development strategy for Dupixent® (dupilumab) in type 2 inflammatory diseases

- * Additional data contribute to the growing body of evidence demonstrating Dupixent's best in class safety profile combined with strong efficacy benefit for atopic dermatitis and further validate it as a standard of care treatment for asthma
- * Dupixent's unique mechanism of action simultaneously inhibits IL-4 and IL-13, which play a key role in type 2 inflammation in multiple diseases
- * Recent evidence further supports additional clinical uses in diseases driven by type 2 inflammation including Eosinophilic Esophagitis and a subset of Chronic Obstructive Pulmonary Disease

PARIS – June 11, 2020 – Sanofi commercial and R&D executives will provide an overview of the growth and development strategy for Dupixent® (dupilumab) in the third of its five-part series to highlight Sanofi's progress in R&D. As announced in December 2019, Sanofi expects to deliver strong growth for Dupixent with the ambition of achieving more than €10 billion in peak sales driven by its selective mechanism of action targeting the type 2 inflammation pathway. Sanofi co-develops and co-commercializes Dupixent with Regeneron.

“By specifically targeting IL-4 and IL-13, Dupixent’s mechanism of action is uniquely suited to help address conditions driven by type 2 inflammation,” said John Reed, M.D., Ph.D., Global Head of Research and Development, Sanofi. *“While atopic dermatitis and asthma are the foundational diseases where Dupixent was first approved for use, great opportunity exists across multiple diseases where type 2 inflammation plays a role. We are therefore aggressively pursuing clinical evaluation of additional indications where patients are urgently awaiting solutions for their unmet medical needs.”*

Today's presentation will detail five potential future line extensions for Dupixent, including:

- **Eosinophilic Esophagitis (EoE)** – It was recently [announced](#) that Part A of the Dupixent EoE pivotal Phase 3 trial met both co-primary endpoints as well as all key secondary endpoints. Dupixent demonstrated significant clinical and anatomic improvements, including the ability to swallow. In the U.S., approximately 160,000 patients with EoE are currently treated, of which an estimated 50,000 have failed multiple treatments.

Part B of the Phase 3 trial is ongoing, and, if the results are positive, regulatory submissions are expected to be filed by the end of 2022. The U.S. Food and Drug Administration (FDA) has granted orphan drug designation to Dupixent for the treatment of EoE. Currently, no FDA-approved treatments are available for this condition.

- **Chronic Obstructive Pulmonary Disease (COPD) with Evidence of Type 2 Inflammation** – Dupixent may benefit COPD patients with evidence of type 2 inflammation. Currently, a Phase 3 study is underway in COPD, with approximately 900 patients enrolled. A second confirmatory study is now being initiated based on a rigorously defined, prespecified futility analysis of data from the ongoing COPD trial. If successful, regulatory submissions would be made in the 2024 timeframe. In the U.S., approximately 300,000 patients with COPD continue to suffer exacerbations despite available treatment options.
- **Prurigo Nodularis (PN)** – PN is a skin disease resulting in intense itching (pruritus) that adversely impacts quality of life, with many patients developing anxiety and depression. Currently, no approved treatments are available for PN, which represents a significant unmet need with approximately 74,000 patients eligible for a biologic in the U.S.

Currently, two Phase 3 studies are underway testing Dupixent, each enrolling 150 patients with PN. Topline trial results are expected in 2021, which could support regulatory filings at the end of 2021.

- **Chronic Spontaneous Urticaria (CSU)** – CSU is a common condition characterized by the recurrent appearance of highly pruritic (itchy) wheals (hives) with or without angioedema. CSU patients experience debilitating hives and pruritus secondary to mast cell and basophil dysregulation. Approximately, 40-50% of patients do not respond to approved treatments including antihistamines and other biologic treatments. Approximately 300,000 patients are eligible for a biologic in the U.S.

Earlier this year, a 240 patient registrational study of Dupixent in CSU was initiated, and if the results are positive, regulatory filings would be submitted in 2022.

- **Bullous Pemphigoid (BP)** – BP is a rare autoimmune skin disease with type 2 inflammatory features, including pruritic plaques and large fluid-filled blisters. Approximately 27,000 patients are chronically treated with oral corticoid steroids who are potentially eligible for a biologic in the U.S.

A pivotal Phase 3 trial testing Dupixent in BP patients has been initiated. If the results are positive, regulatory filings will be submitted in 2023+. The FDA has granted orphan drug designation to Dupixent for the treatment of BP.

All of these potential uses are investigational, and the safety and efficacy of Dupixent in any of these indications has not been evaluated by any regulatory authority.

The virtual investor event will be held today from 3:00-4:30 pm CET / 9:00-10:30 am EDT. Sanofi speakers include:

- Brian Foard, Global Head, Dupixent Franchise
- Frank Nestle, Global Head of Research, Immunology & Inflammation
- Naimish Patel, Global Head of Development, Immunology & Inflammation
- John Reed, Global Head of Research and Development

Joining for Q&A will be Sanofi Chief Executive Officer Paul Hudson, Jean-Baptiste de Chatillon, Sanofi Chief Financial Officer, and Bill Sibold, Global Head of Specialty Care.

Additional information about today's Dupixent presentation can be found at: <https://www.sanofi.com/en/investors/financial-results-and-events/investor-presentations/2020-dupixent-presentation>

About Dupixent

Dupixent is approved in the U.S. to treat patients aged 6 years and older with moderate-to-severe atopic dermatitis that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies; for use with other asthma medicines for the maintenance treatment of moderate-to-severe eosinophilic or oral steroid dependent asthma in patients aged 12 years and older whose asthma is not controlled with their current asthma medicines; and for use with other medicines for the maintenance treatment of CRSwNP in adults whose disease is not controlled. In adolescents 12 years of age or older, it is recommended that Dupixent be administered by or under the supervision of an adult. In children younger than 12 years of age, Dupixent should be administered by a caregiver.

Outside of the U.S., Dupixent is approved for specific patients with moderate-to-severe atopic dermatitis and certain patients with asthma in a number of other countries around the world, including the EU and Japan. Dupixent is also approved in the EU and Japan to treat certain adults with severe CRSwNP. The 200 mg and 300 mg pre-filled pens are currently approved in the EU.

Dupilumab Development Program

In addition to the currently approved indications, Sanofi and Regeneron are also studying dupilumab in a broad range of clinical development programs for diseases driven by allergic and other type 2 inflammatory disorders, including pediatric asthma (6 to 11 years of age, Phase 3), pediatric atopic dermatitis (6 months to 5 years of age, Phase 2/3), chronic obstructive pulmonary disease (Phase 3), bullous pemphigoid (Phase 3), prurigo nodularis (Phase 3), chronic spontaneous urticaria (Phase 3), and food and environmental allergies (Phase 2). These potential uses are investigational, and the

safety and efficacy have not been evaluated by any regulatory authority. Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

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

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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 fact that product may not 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 future litigation and the ultimate outcome of such litigation, and volatile economic and market conditions, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. 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 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, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.