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FDA agrees for priority review of Sanofi's Dupixent for Rhinosinusitis

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Dupilumab is being developed jointly by Regeneron and Sanofi as part of a global collaboration agreement

Regeneron Pharmaceuticals and Sanofi have announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the supplemental Biologics License Application (sBLA) for Dupixent® (dupilumab) as an add-on maintenance treatment for adults with inadequately controlled severe chronic rhinosinusitis with nasal polyps (CRSwNP). Patients with severe CRSwNP often experience recurrence despite previous treatment with surgery and/or systemic corticosteroids. The target action date for the FDA decision is June 26, 2019.

Currently, there are no FDA-approved biologic medicines to treat CRSwNP, a chronic disease of the upper airway predominantly driven by type 2 inflammation and characterized by polyps that obstruct the sinuses and nasal passages.

The sBLA is supported by data from two pivotal Phase 3 trials evaluating the efficacy and safety of Dupixent when combined

with standard-of-care corticosteroid nasal spray in patients with recurring severe CRSwNP despite previous treatment with surgery and/or systemic corticosteroids.

About 60% of patients in the trials had co-morbid asthma. Data from these trials were presented at the Annual Meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) in February 2019. In addition to moderate-to-severe atopic dermatitis and moderate-to-severe asthma, this is the third type 2 allergic inflammatory disease in which Dupixent has demonstrated positive Phase 3 results.

Dupixent is a human monoclonal antibody specifically designed to inhibit signaling of interleukin-4 and interleukin-13 (IL-4 and IL-13). The findings from these trials, as well as from prior trials in atopic dermatitis and asthma, demonstrate that both IL-4 and IL-13 are two key proteins that play a central role in type 2 inflammation, which seems to underlie CRSwNP as well as several other allergic diseases.

Other potential uses for Dupixent, including in CRSwNP, are investigational and the safety and efficacy have not been evaluated by the FDA, the EMA or any other regulatory authority.