

Dupixent[®] (dupilumab) showed positive topline results in two Phase 3 trials of patients with chronic rhinosinusitis with nasal polyps

- * Dupixent significantly reduced nasal polyp size, nasal congestion severity, and need for systemic corticosteroids and/or surgery
- * Dupixent has now demonstrated positive late-stage results in three Type 2 or allergic inflammatory diseases: atopic dermatitis, asthma, and chronic rhinosinusitis with nasal polyps

Paris and Tarrytown, N.Y. – October 16, 2018 – Two pivotal Phase 3 placebo-controlled trials evaluating Dupixent[®] (dupilumab) in adults with inadequately-controlled chronic rhinosinusitis with nasal polyps (“CRSwNP”) met all primary and secondary endpoints.

On the co-primary endpoints for both trials at 24 weeks, patients treated with Dupixent added to a standard-of-care corticosteroid nasal spray experienced a 51% and 57% improvement in their nasal congestion/obstruction severity compared to 15% and 19% improvement with nasal spray alone (placebo) (-1.25 and -1.34 for Dupixent compared to -0.38 and -0.45 for placebo, on a 0-3 scale). Dupixent treated patients had a 27% and 33% reduction in their nasal polyps score compared to a 4% and 7% increase for placebo (-1.71 and -1.89 for Dupixent compared to 0.10 and 0.17 for placebo, on a 0-8 scale that measures bilateral polyps size by endoscopy).

Dupixent also met all secondary endpoints in both trials, including demonstrating a significant reduction in the need for systemic corticosteroids or surgery, and improvements in smell and chronic rhinosinusitis symptoms. In a pre-specified group of patients with comorbid asthma, Dupixent significantly improved lung function and asthma control ($p < 0.0001$ for all primary and secondary endpoints in both trials). Dupixent blocks the IL-4 and IL-13 signaling pathways.

“Dupixent has now demonstrated significant late-stage efficacy in three Type 2 or allergic inflammatory diseases, indicating that IL-4 and IL-13 are required drivers of Type 2 or allergic inflammation in general. With these data, Dupixent has now been shown to address this inflammation across the complete airway, which manifests in the upper respiratory tract as polyps and congestion, and in the lower airway as asthma,” said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. *“We look forward to U.S. regulatory action on our moderate-to-severe asthma application later this month, and are continuing our development program in additional Type 2 or allergic inflammatory diseases with high unmet need including pediatric asthma, pediatric and*

adolescent atopic dermatitis, eosinophilic esophagitis, and food and environmental allergies.”

CRSwNP is a chronic disease in which Type 2 or allergic inflammation causes polyps that obstruct the sinus and nasal passages, leading to severe congestion, nasal discharge, facial pain or pressure, and reduced sense of smell and taste. Persistent symptoms of CRSwNP have a substantial adverse impact on patients’ health-related quality of life. Current treatments are limited and include intranasal corticosteroids, oral corticosteroids and surgery, with high recurrence rates after treatment. Among the patients involved in the two Phase 3 Dupixent trials, more than half had previously undergone surgery for their nasal polyps and nearly three-quarters had used systemic corticosteroids within the past two years.

“Living with inadequately controlled nasal polyps carries a heavy burden with patients experiencing pain, nasal discharge, difficulty breathing and the inability to smell. The standard of care, which includes the use of oral and intranasal corticosteroids, often alongside surgery, has not changed for decades,” said John Reed, M.D., Executive Vice President, Global Head of Research & Development, Sanofi. *“For the first time, we have Phase 3 data showing that a biologic can help address the underlying Type 2 or allergic inflammation that causes chronic rhinosinusitis with nasal polyps and we look forward to working with regulatory authorities around the world to make Dupixent an option for people living with this chronic condition.”*

The rates of adverse events were generally similar across Dupixent and placebo, and no new or unexpected side effects related to Dupixent were observed. The rates of conjunctivitis were: 1.4 percent Dupixent versus 0.8 percent placebo in SINUS-24; 2.7 percent Dupixent every two weeks and 2.0 percent Dupixent every two/four weeks versus 1.3 percent placebo in SINUS-52. Overall rates of serious adverse events were lower with Dupixent: 4.2 percent Dupixent versus 14.4 percent placebo in SINUS-24; 5.4 percent Dupixent every two weeks and 6.8 percent Dupixent every two/four weeks versus 10.0 percent placebo in SINUS-52.

The pivotal Phase 3 trials, known as SINUS-24 (n=276) and SINUS-52 (n=448), had the same co-primary endpoints, which were change from baseline in nasal congestion/obstruction severity based on the patient’s daily morning assessment, and change from baseline in nasal polyposis score (a measure of polyp size) after 24 weeks, as assessed by nasal endoscopy. An additional co-primary endpoint in Japan, a key secondary endpoint in other countries, was change from baseline in sinus opacification, as assessed by computed tomography scan. The trials were randomized double-blind, placebo-controlled trials evaluating Dupixent when added to the corticosteroid mometasone furoate nasal spray (MFNS), compared to MFNS alone. The trials enrolled patients who were 18 years or older with bilateral nasal polyps who, despite treatment with systemic corticosteroids in the previous two years or history of surgery, continued to have ongoing moderate or severe symptoms of nasal congestion, blockage, loss of smell or nasal discharge. Consistent with the overlap seen among patients with Type 2 or allergic inflammatory diseases, more than three-quarters also suffered from other

conditions, including asthma (approximately 59 percent), allergic rhinitis (approximately 58 percent) and NSAID-exacerbated respiratory disease (approximately 28 percent). Patients with co-morbid asthma and CRSwNP tend to have more severe disease.

Detailed results from these trials will be submitted for presentation at future medical meetings, and will form part of the companies' regulatory submissions. The safety and efficacy of Dupixent in CRSwNP is investigational and has not been evaluated by any regulatory authority.

Click [here](#) for information on the dupilumab development program.

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 seven 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.

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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.

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