Press Release

Dupixent approved in the US as the only targeted medicine to treat patients with bullous pemphigoid

- Approval based on pivotal results showing improvements in sustained disease remission and reductions in itch and oral corticosteroid use compared to placebo in adults with BP
- BP is a chronic, debilitating, and relapsing rare skin disease affecting approximately 27,000 adults in the US whose disease is uncontrolled by systemic corticosteroids
- Dupixent is now approved in the US to treat eight distinct diseases with underlying type 2 inflammation, including diseases of the skin, gut, and respiratory system that affect a broad range of patients, from infants to elderly people

Paris and Tarrytown, NY, June 20, 2025. The US Food and Drug Administration (FDA) has approved Dupixent (dupilumab) for the treatment of adult patients with bullous pemphigoid (BP).

BP primarily affects elderly patients, and is characterized by intense itch, painful blisters, and lesions, as well as reddening of the skin. It can be chronic and relapsing with underlying type 2 inflammation. The blisters and rash can form over much of the body and cause the skin to bleed and break down, resulting in patients being more prone to infection and affecting their daily functioning. Available treatment options are limited and can add to overall disease burden by suppressing a patient's immune system.

> ***Patrick Dunn***
> Executive Director, International Pemphigus and Pemphigoid Foundation
> *"People affected by bullous pemphigoid endure unrelenting itch and painful blisters that can damage the skin. Until now, these primarily elderly patients have had limited therapeutic options available, with potential side effects that have often added to their burden. The approval of Dupixent for bullous pemphigoid brings a novel treatment approach to patients and their caregivers, and we are grateful for the tireless efforts of the scientific community who helped us reach this critical milestone."*

> ***Alyssa Johnsen, MD, PhD***
> Global Therapeutic Area Head, Immunology and Oncology Development, Sanofi
> *"Until now, treating bullous pemphigoid was very challenging for elderly patients struggling with the debilitating impact of blisters and lesions, and potentially co-morbid conditions. By addressing two central drivers of the underlying type 2 inflammation that contributes to bullous pemphigoid, Dupixent is the first targeted medicine to allow patients the potential to achieve sustained remission and reduce itch. This approval in the US is important for the thousands of patients living with bullous pemphigoid, and we look forward to working with regulators around the world to bring this innovative medicine to more patients in need."*

The FDA approval is based on data from the pivotal ADEPT phase 2/3 study that evaluated the efficacy and safety of Dupixent compared to placebo in adults with moderate-to-severe BP. Patients were randomized to receive Dupixent 300 mg (n=53) or placebo (n=53) added to standard-of-care oral corticosteroids (OCS). During treatment, all patients underwent a protocol-defined OCS tapering regimen if control of disease activity was maintained. During

the FDA review, the analyses were updated; the FDA-approved results at 36 weeks in the label for Dupixent compared to placebo are:

- 18.3% of patients experienced sustained disease remission compared to 6.1% (12.2% difference; 95% confidence interval: -0.8% to 26.1%), the primary endpoint
- 38.3% of patients achieved clinically meaningful itch reduction compared to 10.5%
- Median cumulative OCS dose was 2.8 grams compared to 4.1 grams

In this elderly population, the most common adverse events (≥2%) more frequently observed in patients on Dupixent compared to placebo were arthralgia, conjunctivitis, blurred vision, herpes viral infections, and keratitis. Additionally, one case of acute generalized exanthematous pustulosis was reported in one patient treated with Dupixent and zero patients treated with placebo.

> ***George D. Yancopoulos, MD, PhD***
> Board co-Chair, President, and Chief Scientific Officer at Regeneron
> *"This approval extends the remarkable ability of Dupixent to transform treatment paradigms for people living with a variety of diseases with underlying type 2 inflammation, from common conditions like asthma and atopic dermatitis, to rarer ones such as eosinophilic esophagitis and prurigo nodularis, and now including bullous pemphigoid. Dupixent has shown the potential to improve the most challenging effects of bullous pemphigoid, while helping some patients achieve sustained disease remission and decreased oral corticosteroid use. Additionally, this approval further reinforces the demonstrated safety profile of Dupixent in a broad age range of patients, from infants to elderly people, and across dermatological, respiratory, and gastrointestinal diseases."*

The FDA evaluated Dupixent under priority review, which is reserved for medicines that represent potentially significant improvements in efficacy or safety in treating serious conditions. Dupixent was previously granted orphan drug designation by the FDA for BP, which applies to investigational medicines intended for the treatment of rare diseases that affect fewer than 200,000 people in the US. Additional regulatory applications are also under review around the world, including in the EU, Japan, and China.

About the Dupixent BP pivotal study

ADEPT was a randomized, phase 2/3, double-blind, placebo-controlled study evaluating the efficacy and safety of Dupixent in 106 adults with moderate-to-severe BP for a 52-week treatment period. After randomization, patients received Dupixent or placebo every two weeks after an initial loading dose, along with OCS treatment. During treatment, OCS taper was initiated after patients experienced two weeks of sustained control of disease activity. OCS tapering could start between four to six weeks after randomization and was continued if disease control was maintained, with the intent of completion by 16 weeks. After OCS tapering, patients were only treated with Dupixent or placebo for at least 20 weeks (rescue treatment could be used if required).

The primary endpoint evaluated the proportion of patients achieving sustained disease remission at 36 weeks. Sustained disease remission was defined as complete clinical remission with completion of OCS taper by 16 weeks without relapse after completion of the OCS taper and no rescue therapy use during the 36-week treatment period. Relapse was defined as appearance of ≥3 new lesions a month or ≥1 large lesion or urticarial plaque (>10 cm in diameter) that did not heal within a week. Rescue therapy could include treatment with high-potency topical corticosteroids, OCS (including increase of OCS dose during the taper or re-initiation of OCS after completion of the OCS taper), or systemic non-steroidal immunosuppressive medications, or immunomodulating biologics.

Select secondary endpoints evaluated at 36 weeks included:

- Proportion of patients with ≥4-point reduction in Peak Pruritus Numerical Rating Scale (scale 0-10)
- Total cumulative OCS dose

About Dupixent

Dupixent (dupilumab) is an injection administered under the skin (subcutaneous injection) at different injection sites. In adults with BP, Dupixent 300 mg is administered every other week after an initial loading dose, and in combination with a tapering course of oral corticosteroids. Dupixent is intended for use under the guidance of a healthcare professional and can be given in a clinic or at home after training by a healthcare professional.

Dupixent is a fully human monoclonal antibody that inhibits the signaling of the interleukin-4 (IL4) and interleukin-13 (IL13) 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 studies, establishing that IL4 and IL13 are two of the key and central drivers of the type 2 inflammation that plays a major role in multiple related and often co-morbid diseases.

Sanofi and Regeneron are committed to helping patients in the US who are prescribed Dupixent gain access to the medicine and receive the support they may need with the DUPIXENT *MyWay*® program. For more information, please call 1-844-DUPIXENT (1-844-387-4936) or visit www.DUPIXENT.com.

Dupixent has received regulatory approvals in more than 60 countries in one or more indications including certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, prurigo nodularis, chronic spontaneous urticaria, chronic obstructive pulmonary disease, and BP in different age populations. More than one million patients are being 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 across more than 60 clinical studies 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 studies, including chronic pruritus of unknown origin and lichen simplex chronicus. 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, develops and commercializes life-transforming medicines for people with serious diseases. Founded and led by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to numerous approved treatments and product candidates in development, most 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Regeneron pushes the boundaries of scientific discovery and accelerates drug development using our proprietary technologies, such as *VelociSuite®,* which produces optimized fully human antibodies and new classes of bispecific antibodies. We are shaping the next frontier of medicine with data-powered insights from the Regeneron Genetics Center® and pioneering genetic medicine platforms, enabling us to identify innovative targets and complementary approaches to potentially treat or cure diseases.

For more information, please visit www.Regeneron.com or follow Regeneron on LinkedIn, Instagram, Facebook or X.

About Sanofi

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and delivering compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY.

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These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Products") and product candidates being developed by Regeneron and/or its collaborators or licensees (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Dupixent® (dupilumab) for the treatment of bullous pemphigoid as discussed in this press release; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), including the studies discussed or referenced in this press release, on any of the foregoing; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, such as Dupixent for the treatment of chronic pruritus of unknown origin, lichen simplex chronicus, and other potential indications; the ability of Regeneron's collaborators, licensees, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; the ability of Regeneron to manage supply chains for multiple products and product candidates and risks associated with tariffs and other trade restrictions; safety issues resulting from the administration of Regeneron's Products (such as Dupixent) and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; 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 Regeneron's Product Candidates; ongoing regulatory obligations and oversight impacting Regeneron's Products, research and clinical programs, and business, including those relating to patient privacy; the availability and extent of reimbursement or copay assistance for Regeneron's Products from third-party payors and other third parties, including private payor 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 payors and other third parties and new policies and procedures adopted by such payors and other third parties; changes in laws, regulations, and policies affecting the healthcare industry; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates (including biosimilar versions of Regeneron's Products); the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators or licensees may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; 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, collaboration, or supply agreement, including Regeneron's agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated; the impact of public health outbreaks, epidemics, or pandemics on Regeneron's business; and risks associated with litigation and other proceedings and government investigations relating to the Company and/or its operations (including the pending civil proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts), risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA® (aflibercept) Injection), the ultimate outcome of any such proceedings and investigations, 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-K for the year ended December 31, 2024, and its Form 10-Q for the quarterly period ended March 31, 2025. 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 or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

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