

### *Dupixent late-breaking positive pivotal data in bullous pemphigoid presented at AAD*

- Five times more adults on Dupixent achieved sustained disease remission at 36 weeks compared to placebo; significant reductions were also seen in disease severity and itch
- Dupixent also significantly reduced oral corticosteroid and rescue medicine use compared to placebo
- Data support the potential of Dupixent to be the first and only targeted medicine to treat bullous pemphigoid, a skin disease with underlying type 2 inflammation; regulatory submissions are under review in the US and the EU

**Paris and Tarrytown, NY, March 8, 2025.** Positive results from the pivotal ADEPT phase 2/3 study evaluating the investigational use of Dupixent (dupilumab) in adults with moderate-to-severe bullous pemphigoid (BP) were shared in a late-breaking oral presentation at the 2025 American Academy of Dermatology (AAD) Annual Meeting. BP is a chronic, debilitating, and relapsing skin disease with underlying type 2 inflammation and characterized by intense itch and blisters, reddening of the skin, and painful lesions.

#### ***Victoria Werth, MD***

Chief of the Division of Dermatology at the Philadelphia Veterans Administration Hospital, Professor of Dermatology and Medicine at the Hospital of the University of Pennsylvania and the Veteran's Administration Medical Center, and principal investigator of the study

*“People with bullous pemphigoid live with unrelenting itch, blisters, and painful lesions that can be debilitating and make it difficult to function daily. Moreover, current treatment options can be challenging for this primarily elderly patient population because they work by suppressing their immune system. By targeting the underlying type 2 inflammation, which is a key driver for bullous pemphigoid, Dupixent is the first investigational biologic to show sustained disease remission and reduce disease severity and itch compared to placebo in a clinical study.”*

The ADEPT study [met all](#) primary and key secondary endpoints, enrolling 106 adults with moderate-to-severe BP who were randomized to receive Dupixent 300 mg (n=53) every two weeks after an initial loading dose 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. Sustained disease remission was defined as complete clinical remission with completion of OCS taper by week 16 without relapse and no rescue therapy use during the 36-week treatment period.

As presented at AAD, results for Dupixent-treated patients at 36 weeks, compared to those treated with placebo, were as follows:

- 20% experienced sustained disease remission, the primary endpoint, compared to 4% (p=0.0114)
- 40% achieved  $\geq 90\%$  reduction in disease severity compared to 10% (p=0.0003)
- 40% achieved clinically meaningful itch reduction compared to 11% (p=0.0006)
- 1678 mg reduction in cumulative OCS exposure (p=0.0220) on average and a 54% lower risk of rescue medication use (p=0.0016)

In this elderly population, overall rates of adverse events (AEs) were 96% (n=51) for Dupixent and 96% (n=51) for placebo. AEs more commonly observed with Dupixent compared to placebo in at least 3 patients included peripheral edema (n=8 vs. n=5), arthralgia (n=5 vs. n=3), back pain (n=4 vs. n=2), blurred vision (n=4 vs. n=0), hypertension (n=4 vs. n=3), asthma (n=4 vs. n=1), conjunctivitis (n=4 vs. n=0), constipation (n=4 vs. n=1), upper respiratory tract infection (n=3 vs. n=1), limb injury (n=3 vs. n=2), and insomnia (n=3 vs. n=2). There were no AEs leading to death in the Dupixent group and 2 AEs leading to death in the placebo group.

In February, the US Food and Drug Administration (FDA) [accepted](#) for priority review the supplemental biologics license application for Dupixent to treat BP. The FDA decision is expected by June 20,2025. 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 applications are also under review around the world, including in the EU.

The safety and efficacy of Dupixent in BP are currently under clinical investigation and have not been evaluated by any regulatory authority.

### **About BP**

BP is a chronic, debilitating, and relapsing skin disease with underlying type 2 inflammation that typically occurs in an elderly population. It is characterized by intense itch and blisters, reddening of the skin, and painful lesions. The blisters and rash can form over much of the body and cause the skin to bleed and crust, resulting in patients being more prone to infection and affecting their daily functioning. Approximately 27,000 adults in the US live with BP that is uncontrolled by systemic corticosteroids.

### **About the Dupixent BP pivotal study**

ADEPT is 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, 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 as long as 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, unless rescue treatment was 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 and no rescue therapy use during the 36-week treatment period. Relapse was defined as appearance of  $\geq 3$  new lesions a month or  $\geq 1$  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), systemic non-steroidal immunosuppressive medications, or immunomodulating biologics.

Select secondary endpoints evaluated at 36 weeks included:

- Proportion of patients achieving  $\geq 90\%$  reduction in Bullous Pemphigoid Disease Area Index (scale: 0-360)
- Proportion of patients with  $\geq 4$ -point reduction in Peak Pruritus Numerical Rating

- Scale (scale 0-10) score
- Total cumulative OCS dose
- Time to first use of rescue medication

### **About Dupixent**

Dupixent (dupilumab) 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.

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, and chronic obstructive pulmonary disease 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, bullous pemphigoid, 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*<sup>®</sup>, 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<sup>®</sup> 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](http://www.Regeneron.com) or follow Regeneron on [LinkedIn](#), [Instagram](#), [Facebook](#) or [X](#).

*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 the world, 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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treatment of adults with bullous pemphigoid as discussed in this press release as well as chronic pruritus of unknown origin, lichen simplex chronicus, and other potential indications; 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 or any potential regulatory approval of Regeneron's Products (such as Dupixent) and Regeneron's Product Candidates; 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; 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 of Regeneron's Products from third-party payers, including private payer 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 payers and new policies and procedures adopted by such payers; 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® (afibercept) 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. 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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