

Sanofi and Regeneron's Dupixent approved in Japan as the first targeted medicine to treat adults with bullous pemphigoid

- Approval in moderate-to-severe patients was based on pivotal study results showing over four times more Dupixent patients experienced sustained disease remission through Week 36 compared with placebo
- BP is a chronic, relapsing skin disease with underlying type 2 inflammation characterized by intense itch alongside painful blisters and other lesions
- BP is the seventh approved indication for Dupixent in Japan

Paris and Tarrytown, NY, March 24, 2026. The Ministry of Health, Labour and Welfare in Japan has granted marketing and manufacturing authorization for Dupixent (dupilumab) for the treatment of adults with moderate-to-severe bullous pemphigoid (BP).

The approval in Japan is based on data from the pivotal LIBERTY-BP-ADEPT phase 2/3 study (clinical study identifier: NCT04206553), which evaluated Dupixent 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. For the primary endpoint, more than four times as many patients on Dupixent experienced sustained disease remission compared to placebo (18% vs. 4%; p=0.0250) at Week 36 in the companies' core dataset used for the regulatory submission in Japan.

Treatment-related adverse events (AEs) occurred in 26% of Dupixent patients and 15% of placebo patients. The treatment-related AE most commonly reported with Dupixent was conjunctivitis (4%).

In addition to BP, Dupixent is approved in Japan in certain patients with atopic dermatitis, asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP), prurigo nodularis, chronic spontaneous urticaria (CSU), and chronic obstructive pulmonary disease (COPD).

About BP

BP is a rare skin disease that 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.

About ADEPT

ADEPT was a randomized, double-blind, placebo-controlled phase 2/3 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 (Q2W) 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 Week 16. After OCS tapering, patients were only treated with Dupixent or placebo for the rest of the study (rescue treatment could be used if required).

The primary endpoint evaluated the proportion of patients achieving sustained disease remission at Week 36. Sustained disease remission was defined as complete clinical remission with completion of OCS taper by Week 16 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.

About Dupixent

Dupixent (dupilumab) is now available in Japan as a 300 mg pre-filled syringe or pre-filled pen for adults with BP. Dupixent is intended for injection under the skin (subcutaneous injection) and is given Q2W after an initial loading dose. It can be given in a clinic or at home by self-administration 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.

Dupixent has received regulatory approvals in more than 60 countries in one or more indications including certain patients with atopic dermatitis, asthma, CRSwNP, eosinophilic esophagitis, prurigo nodularis, CSU, COPD, BP, and allergic fungal rhinosinusitis in different age populations. More than 1.4 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 12,000 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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Sanofi forward-looking statements

This press release contains forward-looking statements within the meaning of applicable securities laws, including 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 and their underlying assumptions regarding the marketing and other potential of the product; regarding potential future events and revenues from the product. Words such as "expect," "anticipate," "believe," "intend," "estimate," "plan," "can," "contemplate," "could," "is designed to," "may," "might," "potential," "objective," "attempt," "target," "project," "strategy," "strive," "desire," "predict," "forecast," "ambition," "guideline," "seek," "should," "will," "goal," or the negative of these and similar expressions are intended to identify forward-looking statements. 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

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This press release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. 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 adults with bullous pemphigoid; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including Dupixent for the treatment of 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 (such as Dupixent) 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 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 to drug pricing regulations and requirements and Regeneron's pricing strategy; other changes in laws, regulations, and policies affecting the healthcare industry; competing products and product candidates (including biosimilar products) that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; 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. 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