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Exdensur (depemokimab) approved in Japan for severe asthma and chronic rhinosinusitis with nasal polyps

- *Exdensur* is the first and only ultra-long-acting biologic in Japan for the treatment of severe asthma and chronic rhinosinusitis with nasal polyps (CRSwNP)
- Approval based on data from the SWIFT and ANCHOR phase III trials showing sustained efficacy in two doses a year versus placebo
- Patients with severe asthma face frequent exacerbations, hospitalisations and disease progression, requiring an urgent need for novel solutions

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GSK plc (LSE/NYSE: GSK) today announced the approval of *Exdensur* (depemokimab) by Japan's Ministry of Health, Labour and Welfare (MHLW) as a treatment for bronchial asthma (limited to severe or refractory patients whose asthma symptoms cannot be controlled with existing treatments) and CRSwNP (limited to patients inadequately controlled with standard treatment).

The MHLW approval was based on data from the SWIFT and ANCHOR phase III trials, which demonstrated the sustained efficacy of a twice-yearly dose of depemokimab versus placebo, both plus standard of care. In SWIFT-1 and SWIFT-2, treatment with depemokimab resulted in significant reductions in asthma exacerbations. Additionally, ANCHOR-1 and ANCHOR-2 showed significant improvements in nasal polyp size and nasal obstruction, two key measures of disease severity.[1,2]

Kaivan Khavandi, SVP and Global Head, Respiratory, Immunology & Inflammation R&D, GSK said: "Building on other recent regulatory milestones, the approval of *Exdensur* in Japan could set a new standard of care for patients with severe asthma or CRSwNP. By delivering sustained suppression of type 2 inflammation in just two doses a year, physicians can now provide an ultra-long-acting option to help protect against asthma exacerbations and the debilitating symptoms of CRSwNP."

Patients in Japan living with severe asthma can experience frequent exacerbations and progression of their disease, leading to hospitalisations and increased overall healthcare costs.[3-6] In addition, patients with CRSwNP face debilitating daily symptoms and almost half remain uncontrolled.[3,7] Depemokimab is a novel therapy that has been developed with an extended half-life, enabling the sustained suppression of disease-driving type 2 inflammation with twice-yearly dosing.[1] These distinct properties could potentially improve patient outcomes while reducing health system burden.

Results from the SWIFT trials showed treatment with depemokimab resulted in a significant 58% and 48% reduction in the rate of annualised asthma exacerbations (asthma attacks) over 52 weeks from SWIFT-1 and SWIFT-2, respectively [rate ratio (95% confidence interval) p-value: SWIFT-1 0.42 (0.30, 0.59) p<0.001 and SWIFT-2 0.52 (0.36, 0.73) p<0.001] (AER depemokimab versus placebo: SWIFT-1 0.46 vs. 1.11 and SWIFT-2 0.56 vs. 1.08 exacerbations per year).[1]

In addition, results from the ANCHOR trials showed an improvement (reduction) from baseline in nasal polyp score (scale: 0-8) at 52 weeks [treatment difference (95% confidence interval) p-value: ANCHOR-1 -0.7 (-1.1, -0.3) p<0.001 and ANCHOR-2 -0.6 (-1.0, -0.2) p=0.004] and in nasal obstruction verbal response scale (scale: 0-3) over weeks 49-52 [treatment difference (95% confidence interval) p-value: ANCHOR-1 -0.23 (-0.46, <0.00) p=0.047 and ANCHOR-2 -0.25 (-0.46, -0.03) p=0.025].[2]

Across these trials, depemokimab was well-tolerated, with patients experiencing a similar rate and severity of side effects as those receiving placebo.[1,2]

Approval in Japan marks the third regulatory approval for depemokimab, following marketing authorisation from the US Food and Drug Administration (FDA) and UK's Medicines and Healthcare products Regulatory Agency (MHRA).[8,9] Depemokimab recently received a positive CHMP opinion in the EU and it is currently under regulatory review in other countries, including in China.[10]

About asthma
Asthma affects more than 260 million people globally, many of whom continue to experience symptoms and exacerbations despite treatment.[11,12] Severe asthma is defined as asthma that requires treatment with medium- to high-dose inhaled corticosteroids plus a second therapy (i.e., systemic corticosteroid or biologic) to prevent it from becoming uncontrolled, or which remains uncontrolled despite therapy.[13] Type 2 inflammation is the underlying cause of pathology in more than 80% of patients with severe asthma, in which patients exhibit elevated levels of eosinophils (a type of white blood cell).[13]

About CRSwNP
CRSwNP is caused by inflammation of the nasal lining that can lead to soft tissue growths, known as nasal polyps.[14,15] People with CRSwNP experience symptoms such as nasal obstruction, loss of smell, facial pain, sleep disturbance, infections and nasal discharge that can significantly affect their emotional and physical well-being.[14,15] Similar to asthma, the majority of cases of CRSwNP (85%) are driven by chronic type 2 inflammation, which is strongly associated with comorbidities, more severe disease, recurring symptoms and tissue remodelling.[14-19]

About *Exdensur* (depemokimab)
Exdensur is the first ultra-long-acting biologic being evaluated for certain respiratory diseases with underlying type 2 inflammation, such as severe asthma. It combines high interleukin-5 (IL-5) binding affinity and high potency with an extended half-life to enable twice-yearly dosing.[1,2] IL-5 is a key cytokine in type 2 inflammation.

Please refer to the updated Product Information (PI) for precautions concerning indications, dosage and administration, and safety information in Japan which will shortly be updated at this link: Japan Pharmaceuticals and Medical Devices Agency.

About the SWIFT phase III trials
Results from the SWIFT trials were presented at the 2024 European Respiratory Society International Conference and published in the *New England Journal of Medicine*.[1,20]

The SWIFT-1 and SWIFT-2 clinical trials assessed the efficacy and safety of depemokimab adjunctive therapy in 382 and 380 participants with severe asthma who were randomised to receive depemokimab or a placebo respectively, in addition to their standard of care (SOC) treatment with medium to high-dose inhaled corticosteroids plus at least one additional controller. The full analysis set in SWIFT-1 included 250 patients in the depemokimab plus SOC arm and 132 in the placebo plus SOC arm; in SWIFT-2, 252 patients were included in the depemokimab plus SOC arm and 128 in the placebo plus SOC arm.[1]

About the ANCHOR phase III trials
Results from the ANCHOR trials were presented at the 2025 American Academy of Allergy, Asthma and Immunology (AAAAI) and World Allergy Organization (WAO) Joint Congress and published in *The Lancet*.[2,21]

ANCHOR-1 included 143 patients in the depemokimab plus SOC arm and 128 in the placebo plus SOC arm; in ANCHOR-2, 129 patients were included in the depemokimab plus SOC arm and 128 in the placebo plus SOC arm. All 528 patients had inadequately controlled CRSwNP, including nasal polyps in both nasal cavities (an endoscopic bilateral NPS ≥5), and had either undergone previous surgery for CRSwNP, had received previous treatment with SCS or were intolerant to SCS. Patients received depemokimab or placebo at six-monthly intervals (26 weeks) in addition to SOC (maintenance intranasal corticosteroids).[2]

About the depemokimab development programme
Depemokimab is currently being evaluated in phase III trials for the treatment of other diseases with underlying type 2 inflammation, including OCEAN for eosinophilic granulomatosis with polyangiitis (EGPA) and DESTINY for hyper eosinophilic syndrome (HES).[22,23] GSK has also initiated the ENDURA-1, ENDURA-2 and VIGILANT phase III trials assessing the efficacy and safety of depemokimab as an add-on therapy in patients with uncontrolled moderate to severe COPD with type 2 inflammation.[24-26]

About GSK in respiratory
GSK continues to build on decades of pioneering work to deliver more ambitious treatment goals, develop the next generation standard of care and redefine the future of respiratory medicine for hundreds of millions of people with respiratory diseases. With an industry-leading respiratory portfolio and pipeline of vaccines, targeted biologics and inhaled medicines, GSK is focused on improving outcomes and the lives of people living with all types of asthma and COPD, along with less understood refractory chronic cough or rarer conditions like systemic sclerosis with interstitial lung disease. GSK is harnessing the latest science and technology with the aim of modifying the underlying disease dysfunction and preventing progression.

About GSK
GSK is a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together. Find out more at gsk.com.

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Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q3 Results for 2025.

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