Stock Exchange Announcement

For media and investors only

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Exdensur (depemokimab) approved by the European Commission for severe asthma with type 2 inflammation and chronic rhinosinusitis with nasal polyps

- *Exdensur* is the first and only ultra-long-acting biologic in the EU to treat respiratory diseases
- Approval based on four phase III trials with statistically significant and clinically meaningful primary data across severe asthma and chronic rhinosinusitis with nasal polyps (CRSwNP)
- An estimated 3 million people live with severe asthma in Europe and patients with CRSwNP face inadequately controlled symptoms

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GSK plc (LSE/NYSE: GSK) today announced the European Commission has approved *Exdensur* (depemokimab) in two indications:

- as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by blood eosinophil count in adults and adolescents 12 years and older who are inadequately controlled despite high dose inhaled corticosteroids (ICS) plus another asthma controller;
- as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control.

The approval is based on data from the SWIFT and ANCHOR phase III trials, which showed sustained efficacy with a twice-yearly dosing regimen for depemokimab. Each of the four trials met their primary or co-primary endpoints with statistically significant and clinically meaningful results, comparing the addition of depemokimab to standard of care versus standard of care alone.[1,2]

Kaivan Khavandi, SVP, Global Head, Respiratory, Immunology & Inflammation R&D, GSK, said: "The approval of Exdensur in the EU means there is now an innovative ultra-long-acting option that offers sustained efficacy over 6 months to protect patients from severe asthma exacerbations and the debilitating symptoms associated with CRSwNP. *Exdensur* may help redefine care for the millions of patients living with these persistent and burdensome conditions, supporting them in achieving their treatment goals with just two doses a year."

Asthma affects more than 42 million people in Europe.[3] About 5-10% of patients experience severe asthma with many continuing to experience exacerbations and reduced quality of life despite treatment.[4] In addition, patients with CRSwNP face debilitating daily symptoms and almost half remain uncontrolled.[5,6] *Exdensur* is a novel therapy that combines high interleukin-5 (IL-5) binding affinity and high potency with an extended half-life, enabling the sustained suppression of disease-driving type 2 inflammation with twice-yearly dosing that could address the continued unmet need in these diseases.[1]

Stephanie Korn, MD, PhD, Head of the Clinical Research Centre IKF Pneumologie Mainz, said: "People living with the burden of severe asthma face persistent exacerbations driven by uncontrolled type 2 inflammation. A new option with twice-yearly dosing that could provide sustained suppression of type 2 inflammation is a promising innovation for patients in Europe with severe asthma who are in urgent need of novel solutions."

Eugenio De Corso, MD, PhD, Professor at University of Perugia, said: "CRSwNP profoundly impacts a patient's daily life, causing debilitating nasal obstruction which can make breathing, smell, sleeping and other fundamental activities a major challenge. An innovative treatment option like *Exdensur,* that could help patients achieve their treatment goals in fewer doses, represents an important advance."

In the SWIFT phase III trials 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 a secondary endpoint from SWIFT-1 and SWIFT-2, patients treated with depemokimab experienced numerically fewer exacerbations requiring hospitalisation and/or emergency department visits (1% and 4%) compared with placebo (8% and 10%), respectively. A pre-specified pooled analysis of the two trials showed there was a 72% reduction in the annualised rate of clinically significant exacerbations requiring hospitalisation and/or ED visits over 52 weeks for depemokimab compared with placebo [rate ratio 0.28, 95% CI (0.13, 0.61), nominal p=0.002] (AER depemokimab 0.02 versus placebo 0.09).[1] The full results from the SWIFT trials were presented at the 2024 European Respiratory Society International Conference and published in the *New England Journal of Medicine*.[1,7]

Additionally, in the ANCHOR phase III trials, treatment with depemokimab resulted in 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] The full 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*.[2,8]

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

Exdensur recently received approval in the US for the treatment of severe asthma, as well as marketing authorisation in the UK and Japan for the treatment of severe asthma and CRSwNP.[9-11]

About the SWIFT phase III trials
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
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 *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 and CRSwNP. 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.

For product and important safety information please consult the country's relevant summary of product characteristics. The EU information is available at: https://www.ema.europa.eu/en/medicines/human/EPAR/exdensur

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).[12,13] 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.[14-16]

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 www.gsk.com.

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