Stock-exchange announcement
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Exdensur (depemokimab) approved in the UK for treatment of asthma with type 2 inflammation and chronic rhinosinusitis with nasal polyps

- First and only ultra-long-acting biologic with twice-yearly dosing to treat respiratory diseases
- UK approval based on data from the SWIFT and ANCHOR phase III trials
- *Exdensur* has shown sustained efficacy to reduce exacerbations, with fewer hospitalisations
- First global approval for *Exdensur*, with upcoming regulatory decisions expected in the US, Japan, EU and China

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GSK plc (LSE/NYSE: GSK) today announced the marketing authorisation of *Exdensur* (depemokimab) by the UK's Medicines and Healthcare products Regulatory Agency (MHRA). In the UK, *Exdensur* is now approved in two indications:

- as an add-on maintenance treatment of asthma in adult and adolescent patients aged 12 years and older with type 2 inflammation characterised by an eosinophilic phenotype who are inadequately controlled on maximum moderate-dose or 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 chronic rhinosinusitis with nasal polyps (CRSwNP) for whom therapy with systemic corticosteroids and/or surgery do not provide adequate 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: "Today's UK approval of *Exdensur*, the first in the world, has the potential to redefine care for millions of patients. This ultra-long-acting biologic delivers sustained efficacy to reduce asthma exacerbations, keep patients out of hospital and help prevent cumulative lung damage in just two doses a year. This is a step change in respiratory treatment, and we look forward to additional regulatory decisions expected in the US, Japan, EU and China."

Asthma affects more than 260 million people globally[3] and about 7 million people in the UK,[4] a portion of whom have type 2 inflammation characterised by an eosinophilic phenotype.[5] Approximately half continue to experience symptoms and exacerbations despite treatment.[6] Asthma exacerbations place a significant resource burden on healthcare systems due to emergency department visits and hospitalisations, with an estimated 22% increase in NHS costs by 2031.[7] With the potential to reduce asthma exacerbations, including those leading to hospitalisations, and alleviate the debilitating symptoms associated with CRSwNP, *Exdensur* could improve patient outcomes while contributing to a reduction in health system burden.

The pooled results from the SWIFT trials showed a 54% reduction in clinically significant exacerbations (asthma attacks) over 52 weeks [rate ratio 0.46, 95% confidence interval (0.36, 0.59), nominal p<0.001] (AER depemokimab = 0.51 exacerbations per year versus placebo = 1.11).[1] Additionally, this pooled analysis showed a 72% reduction [RR 0.28, 95% CI (0.13, 0.61), nominal p=0.002] (AER: depemokimab = 0.02 versus placebo = 0.09) in the secondary endpoint of clinically significant exacerbations requiring hospitalisation or emergency department visit

compared to placebo.[1] In AGILE, an open-label 12-month extension study, depemokimab maintained the results seen in SWIFT-1 and SWIFT-2, confirming the sustained safety and efficacy of a twice-yearly dose of depemokimab over the course of two years.

Pooled results from the ANCHOR trials showed an improvement (reduction) from baseline in nasal polyp score (scale: 0-8) at 52 weeks [treatment difference -0.7, 95% CI (-0.9, -0.4), nominal p<0.001] and in nasal obstruction verbal response scale (scale: 0-3) over weeks 49-52 [treatment difference -0.24, 95% CI (-0.39, -0.08), nominal p=0.003].[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]

Depemokimab recently received a positive CHMP opinion in the EU and it is currently under regulatory review in other countries, including in the US, Japan and China. Decisions on these approvals are expected starting in December 2025 and continuing through H1 2026.

About asthma with type 2 inflammation
Asthma affects more than 260 million people globally, many of whom continue to experience symptoms and exacerbations despite treatment.[8,9] 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.[10]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).[11]

About CRSwNP
CRSwNP is caused by inflammation of the nasal lining that can lead to soft tissue growths, known as nasal polyps.[12,13] People with CRSwNP experience debilitating 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.[12,13] 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]

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] IL-5 is a key cytokine in type 2 inflammation.

More information can be found in the *Exdensur* Summary of Product Characteristics and Patient Information leaflets which will be published on the MHRA Products website within 7 days of approval.

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*.

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*.

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). 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.

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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