Stock Exchange Announcement

For media and investors only

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Exdensur (depemokimab) approved in China for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP)

- *Exdensur* is the first and only ultra-long-acting biologic in China for CRSwNP
- Approval based on ANCHOR trials showing clinically meaningful and statistically significant improvements in nasal polyp size and nasal obstruction
- Patients with CRSwNP continue to face debilitating daily symptoms, underscoring need for novel treatments

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GSK plc (LSE/NYSE: GSK) today announced that China's National Medical Products Administration (NMPA) has approved *Exdensur* (depemokimab) as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control. This follows the NMPA's recent approval for *Exdensur* as an add-on maintenance treatment of severe asthma characterised by an eosinophilic phenotype in adult and paediatric patients aged 12 years and older.[1]

The approval of *Exdensur* in CRSwNP is based on data from the ANCHOR-1 and ANCHOR-2 phase III trials, which 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 [ANCHOR-1 -0.23 (-0.46, <0.00) p=0.047 and ANCHOR-2 -0.25 (-0.46, -0.03) p=0.025].[4] Across these trials, depemokimab was well-tolerated, with patients experiencing a similar rate and severity of side effects as those receiving placebo plus standard of care.[2]

Kaivan Khavandi, SVP, R&D Head Respiratory, Immunology & Inflammation (RI&I), and Head of Translational & Development Sciences, GSK, said: "Given the continued unmet need amongst patients with CRSwNP, today's approval of *Exdensur* could redefine care by protecting from the debilitating symptoms of this disease in just two doses a year. This builds on *Exdensur*'s recent approval in severe asthma, which means more patients in China could have access to this first and only ultra-long-acting biologic."

Almost half of all patients with CRSwNP remain uncontrolled and up to 85% have underlying type 2 inflammation, which is associated with more severe disease.[3-5] An ultra-long-acting therapeutic option that provides sustained suppression of type 2 inflammation could support these patients who continue to face daily symptoms.

Exdensur has also been approved in the US and China for the treatment of severe asthma, as well as in Japan, the EU, and UK for the treatment of severe asthma and CRSwNP.[1,6-9]

About CRSwNP

CRSwNP is caused by inflammation of the nasal lining that can lead to soft tissue growths, known as nasal polyps.[3,10] 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.[3,10] Similar to asthma, the majority of cases of CRSwNP are driven by chronic type 2 inflammation, which is strongly associated with comorbidities, more severe disease, recurring symptoms and tissue remodelling.[3,5,10-13]

About *Exdensur* (depemokimab)

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

For product and important safety information please consult the country's relevant summary of product characteristics.

The EU product information is available at: https://www.ema.europa.eu/en/medicines/human/EPAR/exdensur

The US product information is available at: EXDENSUR-PI-PIL.PDF

About the ANCHOR phase III trials
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*.[2,14]

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).[15,16] 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.[17-19]

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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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 2025.

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