Stock Exchange Announcement

For media and investors only

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Exdensur (depemokimab) approved in China for the treatment of severe asthma

- *Exdensur* is the first and only ultra-long-acting biologic in China for the treatment of severe asthma with an eosinophilic phenotype
- Approval based on SWIFT trials showing significantly lower rates of exacerbations in patients receiving depemokimab versus placebo
- More than 2 million people in China are affected by severe asthma and experience increased risk of exacerbations requiring hospitalisation

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GSK plc (LSE/NYSE: GSK) today announced that China's National Medical Products Administration (NMPA) has approved *Exdensur* (depemokimab) as add-on maintenance treatment of severe asthma characterised by an eosinophilic phenotype in adult and paediatric patients aged 12 years and older.

The approval of *Exdensur* in severe asthma is based on data from the SWIFT-1 and SWIFT-2 phase III trials. In these studies, depemokimab demonstrated sustained exacerbation reduction with two doses per year versus placebo, both plus standard of care.[1]

Kaivan Khavandi, SVP, Global Head, Respiratory, Immunology & Inflammation R&D, GSK, said: "Today's approval for *Exdensur* in China represents an important advance for patients with severe asthma with an eosinophilic phenotype. By providing sustained suppression of type 2 inflammation, an underlying driver of exacerbations and disease progression, *Exdensur* could redefine care in just two doses a year. With *Exdensur* now approved in several major markets, we are focused on transforming the treatment paradigm in severe asthma."

Asthma is a major health burden in China affecting an estimated 46 million adults.[2] Of those, approximately 6% experience severe asthma, which is associated with an increased risk of exacerbations requiring hospitalisation, and higher likelihood of potentially fatal asthma attacks.[2-6] In China, around 15% of people with asthma have experienced an exacerbation requiring a hospital visit in the preceding 12 months.[2]

In the SWIFT-1 and SWIFT-2 trials, treatment with depemokimab resulted in a significant 58% and 48% reduction in the rate of annualised asthma exacerbations (asthma attacks) over 52 weeks, 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). In addition, efficacy and safety results from Chinese patients participating in SWIFT-1 were consistent with the overall population analysis (n=58).[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] Across these trials, depemokimab was well-tolerated, with patients experiencing a similar rate and severity of side effects as those receiving placebo.[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]

The NMPA is also reviewing *Exdensur* 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 does not provide adequate disease control. *Exdensur* has been approved in the US

for the treatment of severe asthma, as well as in Japan, the EU, and UK for the treatment of severe asthma and CRSwNP.[8-11]

About asthma
Asthma affects more than 260 million people globally, many of whom continue to experience symptoms and exacerbations despite treatment.[12,13] 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.[14] 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).[14]

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.[1]

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 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 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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