Press release

For media and investors only

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Exdensur (depemokimab) approved by US FDA for the treatment of severe asthma

- *Exdensur* is the first and only ultra-long-acting biologic with twice-yearly dosing approved for patients with severe asthma with an eosinophilic phenotype
- Approval based on SWIFT trials showing significantly lower rate of annualized asthma exacerbations in patients receiving depemokimab versus placebo
- SWIFT data included reduction in exacerbations requiring hospitalization and/or emergency department visits with depemokimab
- An estimated 2 million Americans live with severe asthma and 50% continue to experience frequent exacerbations and hospitalizations requiring novel solutions

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GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved *Exdensur* (depemokimab-ulaa) as an add-on maintenance treatment of severe asthma characterised by an eosinophilic phenotype in adult and pediatric patients aged 12 years and older.

The FDA approval of *Exdensur* 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. Treatment with depemokimab resulted in a significant 58% and 48% reduction in the rate of annualized 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 hospitalization 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 annualized rate of clinically significant exacerbations requiring hospitalization 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). Across these trials, depemokimab was well-tolerated, with patients experiencing a similar rate and severity of side effects as those receiving placebo.[1]

Kaivan Khavandi, SVP & Global Head, Respiratory, Immunology & Inflammation R&D, GSK said: “Physicians in the US now have the option to provide sustained protection from exacerbations for patients living with severe asthma with an eosinophilic phenotype in just two doses a year. *Exdensur* could redefine patient care and further establish the use of biologics for those who continue to experience exacerbations despite treatment.”

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.

An estimated 2 million Americans live with severe asthma and half continue to experience frequent exacerbations that may lead to hospitalizations, emergency department visits and corresponding increased health system costs.[2,3,4] While biologics have demonstrated benefit in controlling severe asthma, only 20% of eligible patients in the US currently receive one, increasing their risk of exacerbations and worsening disease.[5] Longer dosing intervals have been associated with an increased likelihood that patients would consider a biologic and 73% of physicians believe it would be beneficial.[6,7]

Geoffrey Chupp, MD, Professor of Medicine, Pulmonary, Critical Care and Sleep Medicine, Yale University said: "Current biologic treatments for asthma are often underutilized and frequent injections can be inconvenient for many patients and lead to inconsistent use. There is clearly an opportunity to provide a longer duration of protection from exacerbations between injections for severe asthma patients that reduces the frequency of doses and may improve overall health care utilization. *Exdensur* could empower physicians and patients to potentially achieve their treatment goals with fewer injections."

Tonya Winders, President and CEO, Global Allergy & Airways Patient Platform said: "The struggle for people living with severe asthma is immense, with many silently enduring continued symptom recurrence and exacerbations. An innovative treatment option like *Exdensur* that offers the long-acting protection from exacerbations that severe asthma patients with an eosinophilic phenotype deserve, with the benefit of fewer doses, is truly welcome."

Depemokimab recently received a positive CHMP opinion in Europe, with an approval decision expected in Q1 2026. Regulatory submissions are also under review across the globe, including in China and Japan.

About severe asthma
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.[8] 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).[9]

About *Exdensur* (depemokimab-ulaa)
Exdensur is the first ultra-long-acting biologic being evaluated for certain respiratory diseases with underlying type 2 inflammation, such as severe asthma. It has been developed with an extended half-life to enable twice-yearly dosing.[1]

The US Prescribing Information is available here.

EXDENSUR is indicated for the add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients aged 12 years and older. EXDENSUR is not indicated for the relief of acute bronchospasm or status asthmaticus.

Important Safety Information for EXDENSUR

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions
Hypersensitivity reactions, including anaphylaxis, can occur following administration of EXDENSUR. If a severe hypersensitivity reaction occurs, discontinue EXDENSUR and initiate appropriate therapy.

Acute Asthma Symptoms or Deteriorating Disease
EXDENSUR should not be used to treat acute asthma symptoms or acute exacerbations.

Risk Associated with Abrupt Reduction of Corticosteroid Dosage
Do not abruptly discontinue systemic or inhaled corticosteroids upon initiation of EXDENSUR therapy. Reductions in corticosteroid dose, if appropriate, should be gradual and under the supervision of a healthcare provider. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection
Patients with pre-existing helminth infections should be treated for their infection prior to initiation of EXDENSUR therapy. If patients become infected while receiving EXDENSUR and do not respond to anti-helminth treatment, discontinue EXDENSUR until the infection resolves.

ADVERSE REACTIONS

In patients receiving EXDENSUR, the most common adverse reactions (≥4%) were upper respiratory tract infection, allergic rhinitis, influenza, arthralgia, and pharyngitis. Injection site reactions also occurred.

USE IN SPECIFIC POPULATIONS

The data in pregnant women are insufficient to identify a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Transport of endogenous IgG antibodies and monoclonal antibodies, such as depemokimab-ulaa, across the placenta increases as pregnancy progresses and peaks during the third trimester.

The potential clinical impact of depemokimab-ulaa transmission to the fetus is unknown as the effect of YTE modification on placental transfer is uncertain and may lead to prolonged exposure in an infant. Pregnant women exposed to EXDENSUR, or their healthcare providers, should report EXDENSUR exposure by calling 1-888-825-5249.

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]

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 program
The phase III program consists of SWIFT-1 and SWIFT-2 in severe asthma, with an open label extension study (AGILE), and the ANCHOR-1 and ANCHOR-2 trials in chronic rhinosinusitis with nasal polyps (CRSwNP).[1,10,11] Depemokimab is currently being evaluated in phase III trials for the treatment of other diseases with underlying type 2 inflammation, including OCEAN for EGPA and DESTINY for 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]

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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