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Depemokimab applications accepted for review by the US FDA for asthma with type 2 inflammation and for chronic rhinosinusitis with nasal polyps (CRSwNP)

- If approved, depemokimab will be the first ultra-long-acting biologic with 6-month dosing
- Submissions based on data from positive SWIFT and ANCHOR trials
- SWIFT-1 and -2 showed depemokimab reduced exacerbation and hospitalisation rates as an add-on therapy for patients with asthma with type 2 inflammation versus placebo
- ANCHOR-1 and -2 showed early and sustained reductions in nasal polyp size and nasal obstruction versus placebo

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GSK plc (LSE/NYSE: GSK) today announced the US Food and Drug Administration (FDA) has accepted for review the Biologics License Application for the use of depemokimab in two indications.

The proposed indications are as add-on maintenance treatment of asthma in adult and pediatric patients aged 12 years and older with type 2 inflammation characterised by an eosinophilic phenotype on medium- to high-dose inhaled corticosteroids (ICS) plus another asthma controller and, as add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

The Prescription Drug User Fee Act (PDUFA) date is 16 December 2025.

Kaivan Khavandi , SVP and Global Head, Respiratory, Immunology & Inflammation R&D, GSK , said: "Simultaneous regulatory submissions for two indications highlight our confidence in depemokimab to help reduce the burden of both asthma and CRSwNP for patients and health systems. Our SWIFT and ANCHOR trials support depemokimab's potential to suppress interleukin-5 (IL-5), a known driver of type 2 inflammation, to offer patients sustained inhibition of a key driver of their disease with just two doses per year."

Depemokimab, a monoclonal antibody that targets IL-5, is the first ultra-long-acting biologic to be evaluated in phase III trials and be accepted for regulatory review for use in these conditions.[1-3] Depemokimab's extended half-life, high-binding affinity and potency, support six month (26 week) dosing regimens based on results from the SWIFT and ANCHOR trials.[1-3] In patients with asthma with type 2 inflammation and patients with CRSwNP, these trials met their primary endpoints, showing that depemokimab could offer sustained inhibition of a key driver of their disease, and help achieve key clinical outcomes with a dosing schedule of just two injections per year.[1-3] As demonstrated in studies of other diseases, longer intervals between doses have been shown to overcome barriers to optimal care, such as patient adherence.[4]

IL-5 is a key cytokine (protein) in type 2 inflammation.[1,5,6] Type 2 inflammation is typically identified by blood eosinophil count and is an underlying driver in many diseases. This type of inflammation is present in the majority of patients with difficult to treat asthma and can lead to exacerbations and hospitalisation.[5-7] Type 2 inflammation is also present in up to 85% of people with CRSwNP and is associated with more severe disease and symptoms.[8-12]

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In the United States, more than 26 million people are currently affected by asthma, 40% of whom report having had at least one asthma attack in the previous year which contributes to significant burden this condition exerts on healthcare resources and the lives of patients.[13,14] Each year asthma leads to an estimated 100,000 hospitalisations and nearly 1 million emergency department visits and we are determined to help reduce the burden that respiratory diseases like asthma and CRSwNP exert on patients and healthcare systems.[14]

In the United States, 2.1% of the population are affected by chronic rhinosinusitis, up to 30% of whom have nasal polyps.[8] 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.[8-11] Such symptoms mean the impact of CRSwNP on overall quality of life has been reported to be comparable with other chronic diseases such as COPD, asthma, and diabetes.[9]

Depemokimab is currently not approved for use in any country.

About the depemokimab development programme

The phase III asthma programme consists of SWIFT-1 and SWIFT-2 in asthma with type 2 inflammation, with an open label extension study (AGILE).[1,15] An additional study (NIMBLE) is underway to assess the efficacy and safety of depemokimab when participants with asthma with type 2 inflammation are switched from mepolizumab or benralizumab.[16]

The phase III programme in CRSwNP includes two studies, ANCHOR-1 and ANCHOR-2.[2,3]

Depemokimab is currently being evaluated in phase III trials for the treatment of other IL-5 mediated diseases, including OCEAN for eosinophilic granulomatosis with polyangiitis (EGPA)[17] and DESTINY for hypereosinophilic syndrome (HES).[18]

About SWIFT-1 and SWIFT-2

SWIFT-1 and SWIFT-2 were replicate 52-week, randomised (2:1), double-blind, placebo-controlled, parallel-group, multi-centre Phase III clinical trials.[1] The trials assessed the efficacy and safety of depemokimab as adjunctive therapy in 382 and 380 participants with severe asthma with type 2 inflammation characterised by blood eosinophil count, including adult and adolescent patients, who were randomised to receive depemokimab or a placebo respectively, in addition to their standard of care treatment with medium to high-dose inhaled corticosteroids plus at least one additional controller.[1] Number of subjects included in the Full Analysis of SWIFT-1: depemokimab = 250, placebo = 132 and in SWIFT-2: depemokimab = 252, placebo = 128.[1]

These results have been reported and published in the *New England Journal of Medicine*.[1]

About ANCHOR-1 and ANCHOR-2

ANCHOR-1 and ANCHOR-2 were replicate phase III clinical trials with the same primary and secondary endpoints assessing the safety and efficacy of depemokimab as add-on therapy in adult patients with CRSwNP.[2,3] Both were 52-week, randomised (1:1), double-blind, parallel group, placebo- controlled, multi-centre trials.[2,3] Number of subjects included in the Full Analysis Set of ANCHOR-1: depemokimab = 143, placebo = 128 and in ANCHOR-2: depemokimab = 129, placebo = 128.

Both studies met their co-primary endpoints of change from baseline in total endoscopic nasal polyp score at 52 weeks and change from baseline in nasal obstruction verbal response scale (VRS) mean score from weeks 49 to 52. The overall incidence and severity of treatment-emergent adverse events across ANCHOR-1 and ANCHOR-2 were also similar in patients treated with either depemokimab or placebo.

Full results of ANCHOR-1 and ANCHOR-2 were presented on Saturday 1 March at the 2025 American Academy of

Allergy, Asthma and Immunology (AAAAI) and World Allergy Organization (WAO) Joint Congress in San Diego and simultaneously published in *The Lancet*.[19]

About asthma, CRSwNP and type 2 inflammation

Asthma affects more than 260 million people globally, many of whom continue to experience symptoms and exacerbations despite treatment with high-dose inhaled corticosteroids plus a second controller (and/or systemic corticosteroids).[5,20] Asthma presents a significant financial burden to patients as exacerbations place a resource burden on healthcare systems due to emergency department visits and hospitalisations.[5,21]

CRSwNP is caused by inflammation of the nasal lining that can lead to soft tissue growths, known as nasal polyps.[8,9] 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.[8-11]

There is evidence to show IL-5 has broad effects on other structural and immune and cell types beyond eosinophils, and how they contribute to inflammation, which can lead to lung remodelling and disease progression.[5,6,22-26] Ongoing research is generating further evidence to understand the roles of these cells and their potential contribution to clinical outcomes in patients with respiratory diseases. Type 2 inflammation drives the underlying dysfunction of various immune-mediated conditions. IL-5 is a core cytokine (protein) in type 2 inflammation.[4,5] The presence of type 2 inflammation in asthma or CRSwNP can be detected by blood eosinophil count, which measures the level of a type of white blood cell.[5,10]

About GSK in respiratory

GSK is redefining the future of respiratory medicine as it builds on decades of pioneering work to deliver more ambitious treatment goals and develop the next-generation standard of care, for hundreds of millions of people with respiratory diseases. With an industry-leading respiratory portfolio and pipeline of vaccines, targeted biologics, and inhaled medicines, we are focused on improving outcomes and the lives of people living with all types of asthma and COPD along with less understood diseases like refractory chronic cough or rarer conditions like systemic sclerosis with interstitial lung disease. GSK is harnessing the latest science and technology with the aim to modify underlying disease dysfunction and prevent disease 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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