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GSK announces positive results from phase III severe asthma trials of depemokimab

- Primary endpoints met in SWIFT-1 and SWIFT-2 trials with statistically significant and clinically meaningful reductions in exacerbations over 52 weeks vs. placebo
- Depemokimab has the potential to be the first approved ultra-long-acting biologic with a six-month dosing schedule for severe asthma
- Six-month dosing could simplify treatment to support millions of patients with severe asthma

GSK plc (LSE/NYSE: GSK) today announced positive headline results from the phase III clinical trials SWIFT-1 and SWIFT-2, which assessed the efficacy and safety of depemokimab versus placebo in adults and adolescents with severe asthma with type 2 inflammation characterised by blood eosinophil count.^{1,2} Both SWIFT-1 and SWIFT-2 met their primary endpoints of a reduction in the annualised rate of clinically significant exacerbations (asthma attacks) over 52 weeks.^{1,2} Across both trials the overall incidence and severity of treatment-emergent adverse events were similar in patients treated with either depemokimab or placebo. Further analysis of these data is ongoing.

Depemokimab is the first ultra-long-acting biologic to be evaluated in phase III trials with a binding affinity and high potency for interleukin-5 (IL-5), enabling six-month dosing intervals for patients with severe asthma.^{1,2,3} IL-5 is known to be a key cytokine (protein) in type 2 inflammation.^{4,5} This inflammation, typically identified by elevated blood eosinophil count, is the underlying pathology responsible for more than 80% of people with severe asthma and can lead to unpredictable exacerbations.^{5,6}

Kaivan Khavandi, SVP, Global Head of Respiratory/Immunology R&D, said: “These results add to the established body of evidence that targeted inhibition of IL-5 plays a key role in reducing type 2 inflammation that drives severe asthma exacerbations. Depemokimab could offer the possibility of sustained inhibition of this pathway, with a dosing schedule of just two injections per year. This is important as research shows that 73% of physicians⁷ believe longer dosing intervals would be beneficial to patients who are often juggling multiple therapies.”

Expertise in respiratory diseases and the science of IL-5 has informed the ongoing evidence generation program evaluating the impact of six-month dosing of sustained IL-5 inhibition in patients achieving clinical remission in severe asthma.⁵ The full results of SWIFT-1 and SWIFT-2 will be presented at an upcoming scientific congress and will be used to support regulatory submissions to health authorities worldwide.

Depemokimab is currently not approved anywhere in the world.

About the depemokimab development programme

The phase III programme consists of SWIFT-1 and SWIFT-2 in severe asthma, along with an open label extension study (AGILE).^{1,2,8} SWIFT-1 and SWIFT-2 were replicate 52-week, randomised, double-blind, placebo-controlled, parallel-group, multi-centre phase III clinical trials.^{1,2} The trials assessed the efficacy and safety of depemokimab adjunctive therapy in 375 and 380 participants who were randomised to receive depemokimab or a placebo, in addition to their standard of care treatment with medium to high-dose inhaled corticosteroids plus at least one additional controller.^{1,2}

An additional study (NIMBLE) is underway to assess the efficacy and safety of depemokimab when participants with severe asthma are switched from mepolizumab or benralizumab.⁹

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Depemokimab's extended half-life has the potential to provide sustained inhibition of broad inflammatory functions and is being investigated in a variety of type 2 inflammatory conditions.^{1,2,8-13} Depemokimab is also currently being evaluated in phase III trials across a range of other IL-5 mediated diseases, including eosinophilic granulomatosis with polyangiitis (EGPA), chronic rhinosinusitis with nasal polyps (CRSwNP) and hypereosinophilic syndrome (HES).⁹⁻¹²

About severe asthma and type 2 inflammation

Severe asthma is defined as asthma that requires treatment with high-dose inhaled corticosteroids plus a second controller (and/or systemic corticosteroids) or biologic therapy, to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite therapy.^{5,14} In more than 80% of patients with severe asthma, their condition is driven by type 2 inflammation in which patients exhibit elevated levels of eosinophils (a type of white blood cell).^{5,6} Blood eosinophils count can be measured via a simple blood test. IL-5 is a core cytokine (protein) in type 2 inflammation alongside IL-4 and IL-13.⁵ Type 2 inflammation drives the underlying pathology in a variety of immune-mediated conditions. IL-5 is responsible for the growth, activity and survival of eosinophils.⁵

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, we are 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 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](https://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 under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2023, and GSK's Q1 Results for 2024.

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