Stock-exchange announcement
For media and investors only

Issued: 25 November 2026, London UK

GSK announces positive phase III results for *Exdensur* (depemokimab) in eosinophilic granulomatosis with polyangiitis (EGPA)

- Primary endpoint met, with twice-yearly depemokimab demonstrating comparable efficacy and safety to monthly mepolizumab
- Achieving and maintaining remission is key in EGPA to help reduce risk of relapses and organ damage[1]
- Results support potential as first ultra-long-acting option for EGPA, with regulatory filings planned in H1 2027

GSK plc (LSE/NYSE: GSK) today announced positive headline results from the phase III non-inferiority trial, OCEAN (NCT05263934), [2] which compared the efficacy and safety of twice-yearly depemokimab with monthly mepolizumab in participants with eosinophilic granulomatosis with polyangiitis (EGPA) receiving standard of care.*

The trial met its primary endpoint, showing depemokimab was non-inferior to mepolizumab in terms of achieving disease remission†, a key treatment goal in EGPA. Across the trial, the overall incidence and severity of adverse events were similar in both treatment arms and consistent with depemokimab's existing safety profile.

The results support depemokimab's potential to be the first ultra-long-acting option for patients with EGPA, a chronic inflammatory disease characterised by inflammation of small and medium blood vessels (vasculitis). While rare, EGPA can cause organ damage and may be life-threatening if not treated appropriately.[3,4,5] Patients are often treated with high-dose oral corticosteroids and immunosuppressants. This approach is not sufficient to maintain disease control, leaving patients vulnerable to risks of relapse and complications associated with long-term use of these interventions.[6] GSK's *Nucala* (mepolizumab) was the first approved biologic for EGPA, but there remains a need for additional options to help provide sustained protection against relapses.

Dr Kaivan Khavandi, SVP, Global Head, Respiratory, Immunology & Inflammation R&D, GSK, said: "These data reinforce depemokimab's ultra-long-acting profile, showing that it could help patients achieve disease remission with twice-yearly dosing, reducing the need for corticosteroids and other immunosuppressive therapies. We look forward to sharing the results with regulators to help further evolve the standard of care for people living with EGPA."

Full results of the trial will be submitted for presentation at an upcoming scientific congress, published in a peer-reviewed journal and used to support regulatory submissions to health authorities worldwide.

Depemokimab is not approved for treatment of EGPA anywhere in the world. It is currently approved in the US for the treatment of severe asthma, and EU, Japan, China, and UK for the treatment of severe asthma and chronic rhinosinusitis with nasal polyps (CRSwNP).

About the OCEAN trial
The OCEAN trial is a phase III, randomised, double-blind, double-dummy, parallel group, multi-centre, non-inferiority study to evaluate the efficacy and safety of depemokimab (200 mg) injection every 26 weeks

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* Oral corticoids with or without immunosuppressants
† Remission measured at Birmingham Vasculitis Activity Score (BVAS)=0 and a dose of oral corticosteroids (OCS) ≤ 4mg/day at both Week 36 and Week 52.

compared with mepolizumab (300 mg) injection every 4 weeks in participants with relapsing or refractory EGPA receiving standard of care (oral corticoids with or without immunosuppressants) over a 52-week treatment period. The trial was conducted in 162 participants in 19 countries.

About EGPA

Eosinophilic granulomatosis with polyangiitis (EGPA) is a severe and rare form of vasculitis – a progressive, systemic inflammatory disease that affects an estimated 34 people per million globally.[7] It can affect multiple organ systems, causing life-threatening organ damage if not treated properly.[3, 4, 5] While this disease is poorly understood, triggers in the type 2 inflammatory cascade are established drivers of its pathology.

Clinical manifestations vary between patients and may resemble and/or overlap with other conditions such as asthma, eosinophilic rhinosinusitis, eosinophilia, peripheral neuropathy, lung infiltrate, and purpura, which can make recognition of EGPA challenging. Over 90% of patients with EGPA have asthma[3], 54% of patients have chronic rhinosinusitis with nasal polyps (CRSwNP)[8] and 60–80% have Ear, Nose, and Throat (ENT) complications.[3]

About *Exdensur* (depemokimab)

Exdensur is the first ultra-long-acting biologic approved for certain respiratory diseases with underlying type 2 inflammation, such as severe asthma and CRSwNP. It is also being explored in other conditions, including COPD. It combines high interleukin-5 (IL-5, a protein playing a key role in type 2 inflammation) binding affinity and high potency with an extended half-life to enable twice-yearly dosing.

About GSK's respiratory portfolio

GSK continues to build on decades of pioneering work to deliver more ambitious treatment goals, develop the next generation of treatments, 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 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, and GSK's Q3 Results for 2026.

Registered in England & Wales:
No. 3888792

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[1] Cid, M et al. *Autoimmunity Reviews*, 2026, Nov 3
[2] Study Details | NCT05263934 | Efficacy and Safety of Depemokimab Compared With Mepolizumab in Adults With Relapsing or Refractory Eosinophilic Granulomatosis With Polyangiitis (EGPA) | ClinicalTrials.gov
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