



Issued: 28 January 2025 London UK

## Depemokimab accepted for review by the European Medicines Agency for use in asthma with type 2 inflammation and 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
- ANCHOR-1 and -2 showed depemokimab reduced nasal polyp size and obstruction compared to placebo

---

GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency has accepted for review the Marketing Authorisation Application for the use of depemokimab in two indications.

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

**Kaivan Khavandi, SVP, Global Head of Respiratory/Immunology R&D**, 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 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 interleukin-5 (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.<sup>1</sup> 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.<sup>1-3</sup> In asthma patients and patients with CRSwNP, these trials showed 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.<sup>1-3</sup> Longer intervals between doses have been shown to overcome barriers to optimal care such as patient adherence.<sup>4</sup>

IL-5 is a key cytokine (protein) in type 2 inflammation.<sup>1,5,6</sup> 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.<sup>5-7</sup> Type 2 inflammation is also present in up to 80% of people with CRSwNP and is associated with more severe disease and symptoms.<sup>8-12</sup>

In Europe, more than 42 million people are estimated to have asthma, which contributes to the significant burden this condition has on the lives of patients and healthcare resources, with an estimated annual societal cost of 46 billion euros.<sup>13</sup> CRSwNP is a chronic condition that affects up to 4% of the general population, of whom 40% have uncontrolled disease.<sup>8,9,12</sup>

Depemokimab is currently not approved in any country.

# Stock-exchange announcement / Press release

For media and investors only



## 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).<sup>1,14</sup> 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.<sup>15</sup>

The phase III programme in CRSwNP includes two studies, ANCHOR-1 and ANCHOR-2.<sup>2,3</sup>

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)<sup>16</sup> and DESTINY for hypereosinophilic syndrome (HES).<sup>17</sup>

## 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.<sup>1</sup> The trials assessed the efficacy and safety of depemokimab adjunctive therapy in 382 and 380 adult and adolescent participants with asthma with type 2 inflammation characterised by blood eosinophil count, who were randomised to receive depemokimab or placebo respectively, in addition to their standard of care treatment with medium to high-dose inhaled corticosteroids plus at least one additional controller.<sup>1</sup> Number of subjects included in the Full Analysis of SWIFT-1: depemokimab = 250, placebo = 132 and in SWIFT-2: depemokimab = 252, placebo = 128.<sup>1</sup>

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

## 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. Both were 52-week, randomised (1:1), double-blind, parallel group, placebo-controlled, multi-centre trials.<sup>2,3</sup> 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 will be presented at an upcoming scientific congress.

## 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).<sup>4,17</sup> Asthma presents a significant financial burden to patients as exacerbations place a resource burden on healthcare systems due to emergency department visits and hospitalisations.<sup>18-20</sup>

CRSwNP is caused by inflammation of the nasal lining that can lead to soft tissue growths, known as nasal polyps.<sup>9,12</sup> 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.<sup>9,12</sup>

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.<sup>5,6,21-25</sup> 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.<sup>5,6</sup> 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.<sup>5,8,12</sup>

# Stock-exchange announcement / Press release

For media and investors only



## 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](https://www.gsk.com).

## GSK enquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Sarah Clements	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Lyndsay Meyer	+1 202 302 4595	(Washington DC)
Investor Relations:	Annabel Brownrigg-Gleeson	+44 (0) 7901 101944	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Camilla Campbell	+44 (0) 7803 050238	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

## 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 Q3 Results for 2024.

## Registered in England & Wales:

No. 3888792

## Registered Office:

79 New Oxford Street  
London  
WC1A 1DG

## References

1. Jackson DJ, et al. Six Monthly Depemokimab in Severe Asthma With an Eosinophilic Phenotype. *NEJM*. Published on September 9 at [NEJM.org](https://www.nejm.org).
2. ClinicalTrials.gov. Efficacy and Safety of Depemokimab (GSK3511294) in Participants With Chronic Rhinosinusitis With Nasal Polyps (ANCHOR-1) Available at: <https://clinicaltrials.gov/study/NCT05274750> Accessed January 2025.
3. ClinicalTrials.gov. Efficacy and Safety of Depemokimab (GSK3511294) in Participants With Chronic Rhinosinusitis With Nasal Polyps (ANCHOR-2) Available at: <https://clinicaltrials.gov/study/NCT05281523> Accessed January 2025.
4. Scarsi KK, Swindells S. The Promise of Improved Adherence With Long-Acting Antiretroviral Therapy: What Are the Data? *Journal of the International Association of Providers of AIDS Care (JIAPAC)*. 2021;20.
5. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Updated May 2024. Available at: <https://ginasthma.org/>. Accessed January 2025.
6. Heaney L, et al. Eosinophilic and Noneosinophilic Asthma: An Expert Consensus Framework to Characterize Phenotypes in a Global Real-Life Severe Asthma Cohort. *Chest*. 2021;160(3):814-830.
7. Principe S, et al. Severe asthma: Targeting the IL-5 pathway. *Clin Exp Allergy*. 2021 Aug;51(8):992-1005
8. Laidlaw TM, et al. Chronic Rhinosinusitis with Nasal Polyps and Asthma. *J Allergy Clin Immunol*. 2001;9(3):1133-1141.
9. Bachert C, et al. Burden of Disease in Chronic Rhinosinusitis with Nasal Polyps. *J Asthma Allergy*. 2021;b 11;14:127-134. doi: 10.2147/JAA.S290424. PMID: 33603409; PMCID: PMC7886239.
10. De Corso E, et al. How to manage recurrences after surgery in CRSwNP patients in the biologic era: a narrative review. *Acta Otorhinolaryngol Ital*. 2023;43(Suppl. 1):S3-S13.

# Stock-exchange announcement / Press release

## For media and investors only



11. Chen S, et al. Systematic literature review of the epidemiology and clinical burden of chronic rhinosinusitis with nasal polyposis. *Curr Med Res Opin.* 2020;36(11):1897-1911.
12. Bachert C, et al. EUFORA expert board meeting on uncontrolled severe chronic rhinosinusitis with nasal polyps (CRSwNP) and biologics: Definitions and management. *J Allergy Clin Immunol.* 2021;147(1):29-36.
13. International Respiratory Coalition. Asthma. Available at: <https://international-respiratory-coalition.org/diseases/asthma/> Accessed January 2025
14. ClinicalTrials.gov. An Open-Label Extension Study of GSK3511294 (Depemokimab) in Participants Who Were Previously Enrolled in 206713 (NCT04719832) or 213744 (NCT04718103) (AGILE). Available at: <https://clinicaltrials.gov/study/NCT05243680> Accessed January 2025.
15. ClinicalTrials.gov. A Study of GSK3511294 (Depemokimab) Compared With Mepolizumab or Benralizumab in Participants With Severe Asthma With an Eosinophilic Phenotype (NIMBLE). Available at: <https://clinicaltrials.gov/study/NCT04718389> Accessed January 2025.
16. ClinicalTrials.gov. Efficacy and Safety of Depemokimab Compared With Mepolizumab in Adults With Relapsing or Refractory Eosinophilic Granulomatosis With Polyangiitis (EGPA) Available at: <https://clinicaltrials.gov/study/NCT05263934> Accessed January 2025.
17. ClinicalTrials.gov. Depemokimab in Participants With Hypereosinophilic Syndrome, Efficacy, and Safety Trial (DESTINY) Available at: <https://clinicaltrials.gov/study/NCT05334368> Accessed January 2025.
18. Israel, E, et al. Severe and Difficult-to-Treat Asthma in Adults. *N Engl J Med* 2017;377:965-76.
19. World Health Organisation. Asthma Key Facts. Available at <https://www.who.int/news-room/fact-sheets/detail/asthma> Accessed January 2025
20. European Federation of Allergy and Airways Disease Patients' Association. Available at: [Severely, Asthma! project - European Federation of Allergy and Airways Diseases Patients' Associations \(EFA\)](#) Accessed January 2025
21. Buchheit KM, et al. Mepolizumab targets multiple immune cells in aspirin-exacerbated respiratory disease. *J Allergy Clin Immunol.* 2021;148(2):574-584.
22. Barretto KT, et al. Human airway epithelial cells express a functional IL-5 receptor. *Allergy.* 2020;75(8):2127-2130.
23. Bajbouj K, et al. IL-5 receptor expression in lung fibroblasts: Potential role in airway remodelling in asthma. *Allergy.* 2023;78(3):882-885.
24. Siddiqui S, et al. Eosinophils and tissue remodeling: Relevance to airway disease. *J Allergy Clin Immunol.* 2023;152(4):841-857.
25. Bergantini L, et al. Regulatory T cell monitoring in severe eosinophilic asthma patients treated with mepolizumab. *Scand J Immunol.* 2021;94(1):e13031.