Stock-exchange announcement

For media and investors only

Issued: 12 December 2025, London UK

Nucala (mepolizumab) receives positive CHMP opinion for treatment of chronic obstructive pulmonary disease (COPD)

- Positive opinion based on MATINEE phase III trial showing significant reduction in COPD exacerbations versus placebo in addition to inhaled triple therapy
- *Nucala* is the only monthly biologic studied in a wide COPD population with an eosinophilic phenotype
- *Nucala* could offer a new option to millions of Europeans who remain uncontrolled on inhaled triple therapy and have a raised blood eosinophil count

---

GSK plc (LSE/NYSE: GSK) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the approval of *Nucal*a (mepolizumab), a monoclonal antibody targeting interleukin-5 (IL-5), in adults as an add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA).

The European Commission decision on approval is expected in Q1 2026.

Kaivan Khavandi, SVP & Global Head, Respiratory, Immunology & Inflammation R&D, GSK said: "People living with uncontrolled COPD with an eosinophilic phenotype continue to experience exacerbations that can lead to irreversible lung damage and avoidable hospitalisations and emergency department visits. Preventing these events is crucial to slowing the progression of disease and today's CHMP recommendation brings us closer to providing *Nucala* to patients who are in need of new options."

COPD affects more than 40 million people in Europe and more than 390 million people globally.[1,2] It is estimated that over 35% of COPD patients who are inadequately controlled on inhaled triple therapy have a raised blood eosinophil count (BEC) of at least 300 cells/µL.[3] Recurrent exacerbations accelerate disease progression and add to pressure on healthcare systems through unplanned and unpredictable emergency department visits and inpatient care.[2,4] In 2021 alone, COPD had a societal cost of approximately 164 billion euros and resulted in more than 330,000 deaths in Europe.[5]

The positive opinion is based on data from the MATINEE phase III trial in which mepolizumab demonstrated a statistically significant reduction in the annualised rate of moderate or severe exacerbations compared with placebo, both in addition to inhaled triple therapy [rate ratio 0.79, 95% confidence interval (0.66, 0.94), P=0.01] (AER mepolizumab = 0.80 exacerbations per year versus placebo = 1.01).[6,7] The MATINEE trial studied mepolizumab in a wide spectrum of patients with an eosinophilic phenotype including chronic bronchitis, emphysema only or a combination of both. The incidence of adverse events were similar between mepolizumab and placebo (mepolizumab vs placebo: 74% vs 77%).

In a pre-defined secondary endpoint, the annualised rate of COPD exacerbations requiring ED visits and/or hospitalisation was reduced in the mepolizumab group when compared with placebo [rate ratio 0.65; 95% CI (0.43, 0.96) nominally significant after adjustment for multiplicity] (AER mepolizumab = 0.13 exacerbations per year versus placebo = 0.20).[6] Mepolizumab is the first biologic with pre-specified phase III data showing a reduction in the annualised rate of exacerbations leading to emergency department visits and/or hospitalisation versus placebo.

About MATINEE

MATINEE is a phase III, randomised (1:1), double-blind, parallel-group trial assessing the efficacy and safety of mepolizumab 100 mg as add-on therapy, administered subcutaneously every 4 weeks versus placebo in addition to optimal inhaled triple therapy (dual long-acting bronchodilators plus inhaled corticosteroid).[6,7]

MATINEE assessed the efficacy and safety of mepolizumab for 52–104 weeks, in 804 patients with COPD with evidence of type 2 inflammation, characterised by a raised blood eosinophil count (≥300 cells/µL). Patients could participate with a range of clinical presentations of COPD including chronic bronchitis, emphysema only or a combination of both. The condition of patients ranged in severity from moderate to very severe, or stages 2-4 as assessed by the medically recognised scale of Global Initiative for Chronic Obstructive Lung Disease (GOLD). The full analysis of MATINEE included 403 patients enrolled on the mepolizumab arm and 401 on placebo, all of whom had experienced exacerbations in the previous year despite receiving optimised inhaled maintenance therapy.[6]

About *Nucala* (mepolizumab)
Nucala is a monoclonal antibody that targets and binds to IL-5. *Nucala* has been developed for the treatment of a range of diseases with underlying type 2 inflammation. *Nucala* is currently approved for use in Europe across four indications, including severe asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic granulomatosis with polyangiitis (EGPA) and hypereosinophilic syndrome (HES).[8] It was approved in the US for COPD, its fifth indication, in May 2025.

For product and important safety information please consult the country's relevant summary of product characteristics. The EU and UK Prescribing Information is available at: NUCALA-EPAR-PRODUCT-INFORMATION_EN.PDF

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.

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:	Constantin Fest	+44 (0) 7831 826525	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Sam Piper	+44 (0) 7824 525779	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

Stock-exchange announcement
For media and investors only

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.

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

References

1. European Respiratory Society. (2023). *Introductions*. https://www.ersnet.org/wp-content/uploads/2023/01/Introductions.pdf
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2026 Gold Report. Available at: https://goldcopd.org/2026-gold-report-and-pocket-guide/. Last accessed November 2025.
3. GSK, Optum Analysis DOF (DOF 2024N562932_00).
4. Hurst J R, et al. Susceptibility to Exacerbation in Chronic Obstructive Pulmonary Disease. N Engl J Med. 2010;363:1128-38.
5. International Respiratory Coalition. Chronic obstructive pulmonary disease (COPD). Available at: https://international-respiratory-coalition.org/diseases/copd/. Last accessed November 2025.
6. Sciurba F, et al. Mepolizumab to prevent exacerbations in COPD with an eosinophilic phenotype. N Engl J Med. Apr 2025;392:1710-1720. Available at nejm.org.
7. Pavord ID, et al. Mepolizumab for Eosinophilic Chronic Obstructive Pulmonary Disease. N Engl J Med. Oct 2017;377:1613-1629. DOI: 10.1056/NEJMoa1708208.
8. European Medicines Authority. Nucala prescribing information. Available at: https://www.ema.europa.eu/en/documents/product-information/nucala-epar-product-information_en.pdf. Last accessed November 2025.