Stock Exchange Announcement

For media and investors only

Issued: 6 February 2026, London UK

Nucala (mepolizumab) approved by the European Commission for the treatment of chronic obstructive pulmonary disease (COPD)

- Approval based on results from MATINEE showing significant reduction in the rate of moderate/severe exacerbations versus placebo
- *Nucala* is the first and only monthly biologic in the EU evaluated in a wide COPD population with an eosinophilic phenotype
- MATINEE data showed a reduction in exacerbations leading to emergency department visits and/or hospitalisations versus placebo

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GSK plc (LSE/NYSE: GSK) today announced the European Commission has approved *Nucala* (mepolizumab), a monoclonal antibody targeting interleukin-5 (IL-5), in adults as an add-on maintenance treatment for uncontrolled 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 approval was based on data from the positive MATINEE phase III trial in which mepolizumab showed a clinically meaningful and statistically significant reduction in the annualised rate of moderate/severe exacerbations versus placebo plus standard of care in a wide spectrum of COPD patients with an eosinophilic phenotype.[1]

COPD affects over 390 million people, including about 40 million in Europe.[2,3] Globally, it is projected to be the leading cause of hospital admissions over the next decade.[4] If hospitalised due to COPD, one in ten patients will die during the stay, up to one in four over the next year and half will lose their lives within five years.[5,6] *Nucala* 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.[1]

Kaivan Khavandi, SVP, Global Head, Respiratory, Immunology & Inflammation R&D, GSK, said: "For the first time, adults with uncontrolled COPD characterised by raised blood eosinophils in the EU will have the option for a monthly biologic shown to significantly reduce exacerbations, which can lead to irreversible lung damage, hospitalisations and emergency department visits. *Nucala* could offer relief to the millions of Europeans who need additional options beyond inhaled triple therapy to manage their COPD."

Susanna Palkonen, Director, European Federation of Allergy and Airways Diseases Patients' Associations (EFA), said: "The burden for patients living with COPD is immense, especially for those facing continued exacerbations and repeated hospitalisations. We welcome, and our community celebrates, new treatment options for COPD patients as they are desperately needed."

In MATINEE, 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).[1] 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.

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).[1] The incidence of adverse events were similar between mepolizumab and placebo (mepolizumab vs placebo: 74% vs 77%). The full results from the MATINEE phase III trial were published in *The New England*

Journal of Medicine in April 2025 with further data presented at the 2025 American Thoracic Society International Congress.[1]

In addition to COPD, *Nucala* is approved in Europe across four other diseases driven by underlying type 2 inflammation, including severe asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic granulomatosis with polyangiitis (EGPA), and hypereosinophilic syndrome (HES). It has also been approved for COPD in the US, UK, and China.

About COPD
COPD is a progressive and heterogeneous inflammatory lung disease that includes chronic bronchitis and/or emphysema.[2] It affects more than 390 million people globally and is the third leading cause of death.[2,7] Patients with COPD experience persistent respiratory symptoms such as breathlessness, cough, and sputum along with progressive airflow obstruction due to the chronic inflammation, that impact daily life.[2]

Despite inhaled triple therapy, many patients experience persistent symptoms and exacerbations.[8] A proportion of these patients have elevated type 2 inflammation, characterised by raised BEC. This inflammation contributes to the higher risk of exacerbations, or acute episodes of worsening COPD symptoms, which can result in hospitalisation and irreversible lung damage.[2] Early intervention is important in preventing exacerbations and cumulative lung damage.[2]

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).[1,8] MATINEE assessed the efficacy and safety of mepolizumab in 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 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.[1]

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 approved for use in Europe across five indications, including severe asthma, CRSwNP, EGPA, HES and COPD.[9]

For product and important safety information please consult the country's relevant summary of product characteristics. The EU 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 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 2024, and GSK's Q4 Results for 2025.

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