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***Nucala* (mepolizumab) approved by US FDA for use in adults with chronic obstructive pulmonary disease (COPD)**

- *Nucala* is the only approved biologic studied in a wide COPD population with an eosinophilic phenotype characterised by blood eosinophil count (BEC) starting at 150 cells/ μ L
- Approval based on the positive MATINEE and METREX phase III trials
- MATINEE data included reduction of exacerbations leading to hospitalisation and/or emergency department visits
- Nearly 70% of patients in the US who are inadequately controlled on inhaled triple therapy have a BEC \geq 150 cells/ μ L

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved *Nucala* (mepolizumab) as an add-on maintenance treatment for adult patients with inadequately controlled COPD and an eosinophilic phenotype.

FDA's approval was based on data from the positive MATINEE and METREX phase III trials. Across these trials, mepolizumab showed a clinically meaningful and statistically significant reduction in the annualised rate of moderate/severe exacerbations versus placebo in a wide spectrum of COPD patients with an eosinophilic phenotype.^{1,2} Preventing exacerbations is a key goal of COPD management.³ Exacerbations are devastating for patients, known to cause irreversible lung damage, worsening of symptoms and increased mortality.³ The incidence of adverse events was similar between placebo and mepolizumab groups.^{1,2}

Mepolizumab is the only approved biologic evaluated in patients with an eosinophilic phenotype characterised by a blood eosinophil count (BEC) threshold as low as \geq 150 cells/ μ L.^{1,2} BEC is captured by a simple blood test that measures levels of eosinophils, a type of white blood cell which is a biomarker for type 2 inflammation and indicates a patient's risk of exacerbation.³ Approximately 70% of COPD patients in the US who are inadequately controlled on inhaled triple therapy and continue to exacerbate have a BEC starting at 150 cells/ μ L and above.^{4,5} This represents over a million people at risk of exacerbations, including those leading to emergency department (ED) visits and/or hospitalisations, who could add mepolizumab as an option to their COPD treatment.^{4,5}

Kaivan Khavandi, SVP, Global Head, Respiratory, Immunology & Inflammation R&D, GSK, said: "The approval of *Nucala* in the US provides an important option for COPD patients. Long-term follow-up studies have demonstrated that exacerbations are the single most important predictor of future risk, with particularly poor outcomes in those requiring hospital visits or admissions. Today there is hope for improved care for COPD patients with an eosinophilic phenotype, including those with a BEC threshold as low as \geq 150cells/ μ L who need new options like *Nucala* to support their treatment journey."

Jean Wright, MD, MBA, Chief Executive Officer of the COPD Foundation said: "COPD isn't just a disease, it's a relentless cycle. For individuals living with COPD, managing exacerbations is an ongoing challenge, even with inhaled maintenance therapy. Biologics like mepolizumab are providing renewed optimism for those affected by COPD."

In both MATINEE and METREX trials, mepolizumab demonstrated a statistically significant reduction in the annualised rate of moderate or severe exacerbations compared with placebo, in patients with an eosinophilic phenotype, when added to triple inhaled therapy (MATINEE: rate ratio [RR], 0.79; 95% confidence interval [CI], 0.66 to 0.94; p=0.01) (METREX: rate ratio, 0.82; 95% CI, 0.68 to 0.98; adjusted p=0.04).^{1,2} In a pre-defined secondary

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endpoint in MATINEE, the annualised rate of COPD exacerbations requiring ED visits and/or hospitalisation was reduced in the mepolizumab group when compared with placebo (rate ratio [RR] of 0.65; 95% CI: 0.43, 0.96 [not statistically significant due to a failure of an endpoint higher in the pre-defined testing hierarchy]).¹ COPD-related hospitalisations are a major healthcare challenge and are projected to become the number one cause of medical admissions.⁶ Emergency department visits and inpatient care already account for a large proportion of the annual direct medical costs of COPD, costing the US healthcare system around \$7 billion a year.⁷

Mepolizumab is currently not approved for use in COPD in any other country. Regulatory submissions are under review in China and Europe.

About MATINEE and METREX

Both MATINEE and METREX are phase III, randomised (1:1), double-blind, parallel-group trials 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).^{1,2}

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 blood eosinophil count (≥ 300 cells/ μ L). 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.¹

The full study results from MATINEE were recently published in the *New England Journal of Medicine*¹ with further data presented at the 2025 American Thoracic Society International Congress, including additional sub-analyses in patients with or without cardiovascular comorbidities, varying severities of prior exacerbations, and those with chronic bronchitis, emphysema-only or both.¹

In METREX, the efficacy and safety of mepolizumab was evaluated for 52 weeks in 836 patients randomised (1:1) to mepolizumab or placebo across two groups, the eosinophilic phenotype group (blood eosinophil count of ≥ 150 cells/ μ L at study entry or ≥ 300 cells/ μ L within the past year) or the non-eosinophilic phenotype group (blood eosinophil count of < 150 cells/ μ L at study entry and no evidence of ≥ 300 cells/ μ L within the past year). The study results from METREX were published in 2017 in the *New England Journal of Medicine*.²

About COPD

COPD is a progressive and heterogeneous inflammatory lung disease that includes chronic bronchitis and/or emphysema.³ It affects more than 390 million people globally and is the third leading cause of death.^{8,9} 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.³

Despite inhaled triple therapy, many patients experience persistent symptoms and exacerbations.¹⁰ Exacerbations are acute episodes of worsening COPD symptoms, which can result in hospitalisation and irreversible lung damage.³ Early intervention is important in preventing exacerbations and cumulative lung damage.³

About Nucala

Nucala is a monoclonal antibody that targets and binds to interleukin-5 (IL-5), a key messenger protein (cytokine) in type 2 inflammation. *Nucala* has been developed for the treatment of a range of IL-5 mediated diseases associated with type 2 inflammation. It is currently approved for use in Europe across four IL-5 mediated conditions and in the US across five such conditions.

The US Prescribing Information is available at [NUCALA-PI-PIL-IFU-COMBINED.PDF](#)¹¹

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

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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.

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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 Q1 Results for 2025.

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