Stock-exchange announcement
For media and investors only

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Nucala (mepolizumab) approved in China for use in adults with chronic obstructive pulmonary disease (COPD)

- *Nucala* is the first and only monthly biologic approved in China studied in a wide COPD population with blood eosinophil count (BEC) starting as low as 150 cells/µL
- 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
- Of patients inadequately controlled on inhaled triple therapy, 67% have a blood eosinophil count above 150 cells/µL

GSK plc (LSE/NYSE: GSK) today announced that China's National Medical Products Administration (NMPA) has approved *Nucala* (mepolizumab) as add-on maintenance treatment of adult patients with inadequately controlled COPD characterised by raised blood eosinophils.

The 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 plus standard of care in a wide spectrum of COPD patients with an eosinophilic phenotype. The incidence of adverse events was similar between placebo and mepolizumab groups.

Mepolizumab is the first and only monthly biologic approved in China and evaluated in COPD patients with a BEC starting as low as 150 cells/µL. Around 100 million people in China have COPD.[1] Among those who continue to exacerbate despite inhaled triple therapy, about 67% have a BEC above 150 cells/µL.[2] Recurrent exacerbations accelerates disease progression, higher hospitalisation and readmission rates, increased mortality and greater health system burden.[3,4] COPD deaths in China represent over 30% of global COPD mortality.[1]

Kaivan Khavandi, SVP & Global Head, Respiratory, Immunology & Inflammation R&D, GSK said: "Given the high incidence of COPD in China and a mortality rate that is above the global average, there is a clear need for novel options to address COPD. The approval of *Nucala* offers patients in China a monthly add-on maintenance treatment to reduce exacerbations, including those leading to emergency department visits and/or hospitalisations which account for a large proportion of annual direct medical costs."

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 0.79, 95% confidence interval (0.66, 0.94), P=0.01] (AER mepolizumab = 0.80 exacerbations per year versus placebo = 1.01)] [METREX: rate ratio 0.82, 95% CI 0.68, 0.98, adjusted P=0.04] (AER mepolizumab = 1.40 exacerbations per year versus placebo = 1.71).[5,6] In a pre-defined secondary 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 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).

Mepolizumab is already approved in China as an add-on maintenance treatment for severe eosinophilic asthma in adults and adolescents aged 12 years and older, as well as for adults with chronic rhinosinusitis with nasal polyps and eosinophilic granulomatosis with polyangiitis. It is currently approved for use in COPD in the US. Regulatory

submissions are under review globally, including in Europe where mepolizumab was recently granted a positive CHMP opinion in COPD.

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).[5]

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 an elevated blood eosinophil count (≥300 cells/μL at screening and ≥150 cells/μL in the past year). Patients could participate with a range of clinical presentations of COPD including chronic bronchitis only, emphysema only or a combination of both.

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/μl at study entry or ≥ 300 cells/μl within the past year) or the non-eosinophilic phenotype group (blood eosinophil count of <150 cells/μl at study entry and no evidence of ≥300 cells/μl within the past year).

About COPD
Affecting more than 390 million people globally, COPD is a progressive and heterogeneous inflammatory lung disease that includes chronic bronchitis and/or emphysema.[6] Despite inhaled triple therapy, many patients experience persistent symptoms and exacerbations.[7] Exacerbations are acute episodes of worsening COPD symptoms, which can result in hospitalisation and irreversible lung damage.[6] Early intervention is important in preventing exacerbations and cumulative lung damage.[6]

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 diseases with underlying type 2 inflammation. In addition to COPD, it is currently approved for use in China across three other diseases.

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

The US Prescribing Information is available at NUCALA-PI-PIL-IFU-COMBINED.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.

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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 Q3 Results for 2025.

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