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GSK's application to expand use of Nucala (mepolizumab) for the treatment of COPD accepted for review by the European Medicines Agency

- Submission based on data from MATINEE trial, which showed a statistically significant and clinically meaningful reduction in the annualised rate of moderate/severe exacerbations with mepolizumab versus placebo
- *Nucala* (mepolizumab) could be the first biologic with monthly dosing for patients with COPD, if approved
- More than 40 million people in Europe live with COPD, one of the leading causes of hospitalisation and death

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GSK plc (LSE/NYSE: GSK) today announced that the European Medicines Agency (EMA) has accepted for review its application to expand the use of *Nucala* (mepolizumab), a monoclonal antibody that targets interleukin-5 (IL-5), as an add-on maintenance treatment for patients with chronic obstructive pulmonary disease (COPD) with an eosinophilic phenotype.

The application is supported by results from the positive phase III MATINEE trial, which showed a statistically significant and clinically meaningful reduction in the annualised rate of moderate/severe exacerbations with mepolizumab compared to placebo.[1] The trial recruited patients across a wide spectrum of COPD phenotypes and clinical presentations. These data indicate that mepolizumab, in addition to inhaled maintenance therapy, offers a clinically meaningful benefit to a patient population in need of treatments to reduce their risk of exacerbations. Results of MATINEE will be presented at a future scientific congress.

IL-5 is a key cytokine (protein) in type 2 inflammation which is an underlying driver in many diseases.[2],[3],[4] This type of inflammation is detected in up to 40% of patients with COPD and is a major cause of symptoms and exacerbations that can lead to hospitalisation and/or emergency room visits.[2-4]

COPD affects more than 390 million people globally[5] and over 40 million people in Europe[6]. It is one of the leading causes of hospitalisation in many countries[7]. In 2021 alone, COPD had a societal cost of approximately 164 billion euros and resulted in more than 330,000 deaths in Europe.[6] Recurrent exacerbations accelerate disease progression and further increase the risk of hospitalisation, adding to pressures on healthcare systems through emergency department visits and inpatient care.[5],[8]

If approved, mepolizumab could be the first biologic with monthly dosing for patients with COPD.

Mepolizumab is currently approved for use in Europe across four IL-5 mediated conditions. These include two respiratory indications as an add-on treatment for severe refractory eosinophilic asthma in adults, adolescents and children aged 6 years and older and as an add-on therapy with intranasal corticosteroids for the treatment of adult patients with severe chronic rhinosinusitis with nasal polyps for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control. Indications also include the use of mepolizumab as an add-on treatment for patients aged 6 years and older with relapsing-remitting or refractory eosinophilic granulomatosis with polyangiitis (EGPA) and as an add-on treatment for adult patients with inadequately controlled hypereosinophilic syndrome without an identifiable non-haematologic secondary cause.[9]

Mepolizumab is currently not approved for use in COPD in any country.

About the *Nucala* (mepolizumab) development programme for COPD

First approved in 2015 for severe asthma with an eosinophilic phenotype in the US, mepolizumab is a monoclonal antibody that targets and binds to interleukin-5 (IL-5), a key messenger protein (cytokine) in type 2 inflammation. Mepolizumab has been developed for the treatment of a range of IL-5 mediated diseases associated with type 2 inflammation.

The mepolizumab programme in COPD is comprised of three clinical trials. The first two studies, METREX and METREO, completed in 2017. MATINEE was designed to supplement METREX and METREO, building on our learnings from these studies and IL-5 science to identify the patients who could benefit the most from mepolizumab and support future submissions and approvals for use in this indication.[10]

MATINEE is a phase 3, randomized (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 for 52-104 weeks, versus placebo in addition to inhaled triple therapy (dual long-acting bronchodilators plus inhaled corticosteroid) in 804 patients with COPD, a history of exacerbations, and evidence of type 2 inflammation characterised by raised blood eosinophil count.[1]

The primary endpoint was met with the addition of *Nucala* to inhaled maintenance therapy, showing a statistically significant and clinically meaningful reduction in the annualised rate of moderate/severe exacerbations versus placebo with patients treated for 52-104 weeks.[1]

For product and important safety information please consult the country relevant summary of product characteristics. European information available at: https://www.ema.europa.eu/en/documents/product-information/nucala-epar-product-information_en.pdf

About chronic obstructive pulmonary disease (COPD) and type 2 inflammation

COPD is a progressive and heterogeneous inflammatory lung disease that includes chronic bronchitis and/or emphysema.[5] Type 2 inflammation is present in a variety of immuno-inflammatory conditions and is a major contributor to symptoms and exacerbations in up to 40% of people with COPD.[11] 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.[5]

Despite inhaled triple therapy, many patients experience persistent symptoms and exacerbations, meaning there is a need for targeted therapies to address the underlying pathophysiology linked to disease progression. Exacerbations are acute episodes of worsening COPD symptoms and can result in hospitalisation and irreversible lung damage that leads to progressive lung function decline. For patients, this can result in a vicious cycle of deterioration in overall physical health, which leads to worsening of symptoms and quality of life, and increased mortality. Early intervention is important in preventing exacerbations and cumulative lung damage.[5]

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. 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 key cytokine (protein) in type 2 inflammation. The presence of type 2 inflammation can be detected by blood eosinophil count, which measures the level of a type of white blood cell. [2-4]

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, we are 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 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

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GSK enquiries

Media:	Tim Foley	+44 (0) 20 8047 5502	(London)
	Dan Smith	+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) 7831826525	(London)
	Annabel Brownrigg-Gleeson	+44 (0) 7901 101944	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 4855	(Philadelphia)

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