Nucala (mepolizumab) approved in China for use in severe asthma with an eosinophilic phenotype

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For media and investors only

- Mepolizumab is the first targeted anti-Interleukin-5 (IL-5) biologic available in China as an add-on maintenance treatment for severe eosinophilic asthma

- Asthma is a major health priority in China with millions affected by severe disease

- Approval based on a separate phase III trial among Chinese patients reinforcing mepolizumab's efficacy and safety data

GSK plc (LSE/NYSE: GSK) today announced that the China National Medical Products Administration has approved Nucala (mepolizumab), as an add-on maintenance treatment for severe eosinophilic asthma in adults and adolescents aged 12 years and older. Nucala is the first anti-Interleukin-5 (IL-5) targeting treatment approved for use in China for adult and adolescent patients with this condition.

Asthma is a major health burden in China affecting an estimated 46 million adults. 1 Of those, approximately 6% experience severe asthma, which confers the most substantial impact on daily living, is associated with an increased risk of exacerbations requiring hospitalisation, and higher likelihood of potentially fatal asthma attacks. 1-5 In China, 15.5% of people with asthma have experienced an exacerbation requiring a hospital visit in the preceding 12 months. 1

Kaivan Khavandi, Senior Vice President, Global Head, Respiratory and Immunology, R&D, said:

> We are delighted with this approval, supported by evidence in a Chinese population. Millions of people in China with severe

eosinophilic asthma can now potentially benefit from the advance in management that Nucala could offer – a testament to GSK's ongoing commitment to redefine respiratory disease management globally.

Guidelines for bronchial asthma prevention and management (2020 edition) from the Asthma group of the Chinese Thoracic Society reference the current unmet need among Chinese patients with this condition. 6 The guidelines also reference evidence for targeted biologic therapy that could reduce exacerbations, emergency or hospitalisation rates, oral corticosteroid use, and also improve asthma control and lung function.

The approval for use in severe asthma is based on positive data from a separate phase III trial among Chinese patients. 7,8 The results from the Chinese study reinforce existing data for mepolizumab in patients with severe asthma. 8-13 Adverse events were consistent with the known safety profile for mepolizumab with no new emerging safety issues specific to Chinese patients. 9, MENSA 10, SIRIUS 11 and MUSCA. 12 These trials established the efficacy and safety profile of mepolizumab in patients with severe asthma with an eosinophilic phenotype with safety data coming from pivotal, long-term and real-world studies. 9-14

The 52-week phase III trial in Chinese patients with severe asthma studied the effect of mepolizumab relative to placebo, as add-on on the primary endpoint of reduction in the annual rate of clinically significant exacerbations (CSE). 7,8 Patients in the trial who received mepolizumab compared to those who received placebo experienced 65% fewer CSE's (0.45 vs.1.31 events/year, HR [95% CI]: 0.35 [0.24, 0.50] p

This is the second indication for mepolizumab in China, with approval for use in adults with eosinophilic granulomatosis with polyangiitis (EGPA) received in 2021. Epidemiological, clinical and pathophysiological studies show that patients with EGPA usually also have asthma, which is often severe). 15

About Nucala (mepolizumab)

First approved in 2015 for severe asthma with an eosinophilic phenotype in the US, Nucala is the first-in-class monoclonal antibody to target IL-5. 16,17 Mepolizumab as the first anti-IL-5 targeting

biologic approved in China is an important medical advance in the management of asthma. IL-5 is an inflammatory signalling molecule that is central to the development, maturation and activation of eosinophils, a type of white blood cell implicated in the pathogenesis in the majority of cases of severe asthma. 18 Evolving evidence suggests IL-5 has an impact on other cell types beyond eosinophils, leading to epithelial barrier dysfunction, airways remodelling and disease progression. 19-25 Mepolizumab binds directly to and inhibits IL-5 molecules. 16,17

Nucala is currently approved in China for use in adults with EGPA and was included on the National Reimbursement Drug List in January 2023. Nucala has been studied in over 4,000 patients in 41 clinical trials across several IL-5 mediated conditions and was the first treatment approved in the US and Europe, across four IL-5 medicated conditions: severe asthma with an eosinophilic phenotype, EGPA, hypereosinophilic syndrome and chronic rhinosinusitis with nasal polyps. 16,17 Nucala has been approved in the US, the European Union and over 25 other markets as an add-on maintenance treatment for patients with severe asthma.

For product and important safety information please consult the country relevant summary of product characteristics.

EU and UK available at:
https://www.ema.europa.eu/en/documents/product-information/nuc...

US available at:
http://www.accessdata.fda.gov/drugsatfda_docs/label/2019/76112...

Severe asthma is defined as asthma which requires treatment with high-dose inhaled corticosteroids plus a second controller (and/or systemic corticosteroids) to prevent it from becoming ‘uncontrolled’ or which remains ‘uncontrolled’ despite this therapy. 8-11 Severe asthma patients can also be categorised by long-term oral corticosteroid use. In a sub-set of severe asthma patients, type two inflammation and over-production of eosinophils (a type of white blood cell) leads to a range of symptoms and longer-term lung remodelling. 16

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.

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 under Item 3.D 'Risk factors" in the company's Annual Report on Form 20-F for 2022, and Q3 Results for 2023.

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