China National Medical Products Administration accepts regulatory submission for Nucala (mepolizumab) in severe eosinophilic asthma

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For media and investors only

GSK plc (LSE/NYSE: GSK) today announced that the China National Medical Products Administration has accepted for review a new drug application for Nucala (mepolizumab) as an add-on maintenance treatment for severe eosinophilic asthma (SEA). If approved, Nucala would be the first targeted anti-Interleukin-5 (IL-5) treatment in China for adult and adolescent patients with this condition.

The application is based on positive data from a phase III trial among Chinese patients 1 and the global SEA development programme, which included three key clinical trials – DREAM 2, MENSA 3 and SIRIUS 4– that established the efficacy and safety profile of mepolizumab for severe eosinophilic asthma patients. The 52-week phase III trial in Chinese patients studied the effect of mepolizumab as adjunctive therapy in patients with SEA with a primary endpoint of reduction, relative to placebo, in the annual rate of clinically significant exacerbations. 1 The efficacy and safety of mepolizumab in the Chinese population were shown to be consistent with that in a non-Chinese population with SEA. 2-5

Asthma affects an estimated 46 million adults in China, with 6% experiencing severe asthma. 6-8 Patients with SEA have an increased risk of exacerbations requiring hospitalisation or of experiencing a potentially fatal asthma attack. 9,10 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 SEA. 11

Nucala is currently approved in China for use in adults with eosinophilic granulomatosis with polyangiitis (EGPA) and was included on the National Reimbursement Drug List in January 2023. Nucala is not currently approved in China for the treatment of SEA.

About Nucala (mepolizumab)

First approved in 2015 for SEA in the US , Nucala is the first-in-class monoclonal antibody to target IL-5. It is believed to work by preventing IL-5 from binding to its receptor on the surface of eosinophils, reducing blood eosinophils and maintaining them within normal levels. 12

Nucala has been studied in over 4,000 patients in 41 clinical trials across several eosinophilic indications and was the first treatment approved in the US across four eosinophil-driven diseases: SEA, EGPA, hypereosinophilic syndrome and chronic rhinosinusitis with nasal polyps. Nucala has been approved in the US, the European Union and over 25 other markets, as an add-on maintenance treatment for patients with SEA.

About severe eosinophilic asthma

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. 2-5 Severe asthma patients can also be categorised by long-term oral corticosteroid use. In a sub-set of severe asthma patients, the over-production of eosinophils (a type of white blood cell) is known to cause inflammation in the lungs; this is known as SEA. 13

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/company.

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, GSK’s Q4 Results for 2022 and any impacts of the COVID-19 pandemic.

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