GSK’s regulatory submission accepted for review by Japanese regulator for use of Nucala (mepolizumab) in adults with chronic rhinosinusitis with nasal polyps

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For media and investors only

GSK plc (LSE/NYSE: GSK) today announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has accepted for review a supplementary new drug application (sJNDA) for Nucala (mepolizumab), a monoclonal antibody that targets interleukin-5 (IL-5), as a treatment for chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients.

The sJNDA is based on results of the pivotal phase III MERIT trial which studied the efficacy and safety of mepolizumab over a 52-week period in a population of Japanese, Chinese and Russian patients with inadequately controlled CRSwNP or eosinophilic chronic rhinosinusitis (ECRS) as well as data from the global phase III SYNAPSE study, which explored the effect of mepolizumab vs. placebo in more than 400 patients with CRSwNP.1,2

CRSwNP/ECRS affects 2-4% of the general population.2 In Japan, it is estimated that there are 2 million people with chronic sinusitis, of which about 200,000 are subject to surgery due to nasal polyps.3 CRSwNP is caused by chronic inflammation of the nasal lining.2 Elevated levels of IL-5 are associated with CRSwNP as a result of T2 inflammation, which can cause soft tissue growth, known as nasal polyps that develop in the sinuses and nasal cavity.2 People with CRSwNP experience symptoms such as nasal obstruction, loss of smell, facial pressure, sleep disturbance and nasal discharge.2

Surgery may be indicated for severe cases. However, polyps have a strong tendency to reoccur, often leading to repeat surgery.2

If approved, mepolizumab would be the first anti-IL-5 biologic for adult patients with inadequately controlled CRSwNP in Japan. Mepolizumab is approved in Japan as a treatment for bronchial asthma in children aged 6 years or older and in adults with refractory asthma whose symptoms are inadequately controlled with standard treatment and also for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA) inadequately responding to the current treatment.

The primary endpoints were change from baseline in total endoscopic nasal polyp score at week 52 and change from baseline in mean nasal obstruction visual analogue scale (VAS) score during the 4 weeks prior to week 52.1 The co-primary endpoints were met, and the efficacy and safety of mepolizumab in the Japanese population were consistent with results from global trials.1,2

About Nucala (mepolizumab)

First approved in 2015 for severe eosinophilic asthma (SEA) in the US, mepolizumab is a unique monoclonal antibody that targets and binds to interleukin-5 (IL-5), the major cytokine responsible for the maturation and activation of eosinophils.4 The administration of mepolizumab has shown to reduce the number of blood eosinophils and maintain them within normal levels (normal level of blood eosinophils being less than 500 eosinophils/microliter).4 Mepolizumab has been developed for the treatment of a range of IL-5 mediated diseases identified by elevated blood eosinophil counts.4 Mepolizumab has been studied in over 4,000 patients in 41 clinical trials across several indications.

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 Q2 Results for 2023 and any impacts of the COVID-19 pandemic.

National Library of Medicines (U.S.) (2021, February – 2023, April) Efficacy and Safety of Mepolizumab in Adults With Chronic Rhinosinusitis With Nasal Polyps (CRSwNP)/ Eosinophilic Chronic Rhinosinusitis (ECRS) (MERIT) NCT04607005 https://classic.clinicaltrials.gov/ct2/show/NCT04607005 Han JK, et al. Mepolizumab for chronic rhinosinusitis with nasal polyps (SYNAPSE): a randomised, double-blind, placebo-controlled, phase 3 trial. The Lancet Respiratory Medicine 2021 9 (10), 1141-1153 JESREC Study About refractory eosinophilic sinusitis available at https://jesrec.jp/general/disease.html(last accessed September 2023) Nucala (mepolizumab) SmPC available at Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) last accessed August 2023.

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