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GlaxoSmithKline (GSK) has received approval from the US Food and Drug Administration (US FDA) for its Biologics License Application (BLA) for Nucala (mepolizumab) as an add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Nucala is not approved for the treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus.

Nucala is the first and only approved biologic therapy that targets interleukin-5 (IL-5), which plays an important role in regulating the function of eosinophils, an inflammatory cell known to be important in asthma. It is administered as a 100mg fixed dose subcutaneous injection every four weeks. Patients will receive Nucala in addition to their normal medications for severe asthma, which include high-dose inhaled corticosteroids plus at least one additional asthma control medicine, and may include oral corticosteroids.

This is said to be the first marketing authorization granted for mepolizumab anywhere in the world.

Mr Eric Dube, senior vice-president and head, GSK Global Respiratory Franchise, said, "Following today's approval, GSK can now offer, as part of our overall respiratory portfolio, a first-in-class biologic treatment for severe asthma patients whose condition is driven by eosinophilic inflammation. Our research has allowed us to better understand the specific role eosinophils play in severe asthma. We are proud of our contribution to this emerging area of science that has led to the approval of the first anti-IL5 treatment. We aim to offer this medicine to patients as soon as possible."

Patients who were shown to benefit from treatment with mepolizumab in the Phase III clinical trials were those with blood eosinophil levels of 150 cells/mcL or greater just prior to treatment. Further information on eosinophil data is included within the approved prescribing information.

Professor Ian Pavord, University of Oxford, lead investigator of the first proof of concept trial for mepolizumab and an investigator for the Phase III MENSA study said, "Severe asthma is a debilitating condition in which patients are at high risk of frequent and serious asthma attacks. Half of all severe asthma patients have at least one urgent care visit per year. As a clinician, the prospect of a treatment that can specifically target the underlying cause of the disease for patients whose condition is driven by eosinophilic inflammation is exciting."