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Singapore: GlaxoSmithKline (GSK) has announced that the Japanese Ministry of Health, Labour and Welfare (MHLW) has granted approval for Nucala (mepolizumab) as a treatment for bronchial asthma in patients with refractory asthma whose symptoms are inadequately controlled with standard treatment. Nucala is licensed in Japan for adults and adolescents aged 12 years or older.

Nucala is the first medicine in a new class of anti-interleukin-5 (IL-5) biologic therapies. IL-5 plays an important role in regulating the function of eosinophils, inflammatory white blood cells known to be important in asthma. The medicine is administered as a 100 mg fixed dose subcutaneous injection once every four weeks. Patients will receive the treatment in addition to their existing respiratory medication, which comprises high-dose inhaled corticosteroids plus additional medicines, and may include maintenance oral corticosteroids.

Approval in Japan comes just four months after the approval of Nucala in the US - the first approval of an anti-IL-5 treatment anywhere in the world.

Mr Philippe Fauchet, president, GSK Japan said, "As the market leader in respiratory medicine, GSK has been focused on gaining approval and launching its new respiratory medicines to meet the needs of patients in Japan. Approval of Nucala not only complements our respiratory portfolio but also gives us the opportunity to make a difference to the lives of more patients in Japan. It is our aim to make Nucala available in Japan as soon as possible to support the needs of a significant group of severe asthma patients whose condition is driven by eosinophilic inflammation, which is difficult to control."

The MHLW assessment of mepolizumab was based on data from the global clinical development programme, including the pivotal DREAM (MEA112997), MENSA (MEA115588) and SIRIUS (MEA115575) studies, which investigated the efficacy and safety of mepolizumab in patients with severe eosinophilic asthma.

All patients in the phase III MENSA and SIRIUS studies had peripheral blood eosinophil levels greater than or equal to 150 cells/Î¼L at initiation of treatment or greater than or equal to 300 cells/Î¼L within the past 12 months.