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GSK receives nod for Nucala (mepolizumab) to treat EGPA

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FDA approves first drug for Eosinophilic Granulomatosis with Polyangiitis, a rare disease formerly known as the Churg-Strauss Syndrome

US Food and Drug Administration (FDA) have given approval to Nucala (mepolizumab) of GlaxoSmithKline.

Nucala deliver the first targeted treatment for eosinophilic granulomatosis with polyangiitis (EGPA), previously known as Churg-Strauss syndrome.

GSK submitted a supplemental Biologics License Application (sBLA) for mepolizumab, an interleukin-5 (IL-5) antagonist, in June 2017.

Eric Dube, Senior Vice President & Head, GSK Global Respiratory Franchise, said: "Following physician and patient experience with Nucala in severe eosinophilic asthma, we are thrilled that the FDA has expanded the use of this medicine to patients with EGPA, another eosinophil-driven disease, enabling GSK to make it available to patients.

This approval follows the positive results of the largest prospective treatment study conducted in EGPA to date, and now for the first time physicians have a targeted treatment option for this debilitating condition." He stated further

Mepolizumab is not approved for the treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus.

The approval for EGPA is based on results from the pivotal, 52-week, Phase III MIRRA1 study, conducted as a collaboration between GSK and the National Institute of Allergy and Infectious Diseases, part of the US National Institutes of Health.

The MIRRA study evaluated the efficacy and safety of 300mg of mepolizumab administered subcutaneously every four weeks versus placebo as add-on therapy to standard of care in 136 patients with relapsing and/or refractory EGPA.

Both co-primary endpoints (accrued time in remission and proportion of patients achieving remission at both weeks 36 and 48) were statistically significant in favour of mepolizumab.

All six secondary endpoints (investigating relapse, remission, and corticosteroid use) were met in favour of mepolizumab.

The percentage of patients experiencing on-treatment adverse events was comparable between the two treatment groups (97% mepolizumab versus 94% placebo).

Injection site reactions (e.g., pain, erythema, and swelling) occurred at a rate of 15% in patients receiving mepolizumab compared with 13% in patients receiving placebo.

Eighteen percent of patients receiving mepolizumab reported serious adverse events compared with 26% in the placebo group, with the most frequently reported being asthma worsening/exacerbation (3% versus 6%).

Dr. Peter A. Merkel, Chief, and Division of Rheumatology at Perelman School of Medicine, University of Pennsylvania & MIRRA study site investigator said: "Patients suffering from EGPA too often face a frustrating journey from a delay in receiving a proper diagnosis to having few effective treatment options with an acceptable safety profile."

According to him, Rheumatologists, immunologists, and pulmonologists have an important role in properly diagnosing and treating patients with EGPA. Today's approval of mepolizumab provides specialists with the ability to offer a targeted treatment to appropriate patients with this complex disease.

Dr. Michael E. Wechsler, Professor of Medicine at National Jewish Health in Denver, Colorado, US & Principal Investigator of the MIRRA study, said: "Patients with EGPA often suffer from recurrent relapses that place them at greater risk of permanent tissue and organ damage. Clinical data demonstrated that mepolizumab increased accrued time in remission, reduced the frequency of relapse and flares, and enabled patients to have their dose of corticosteroid reduced compared to placebo in patients already receiving standard of care. These are key treatment goals and this approval is an important milestone both for treating physicians and for patients."

Nucala for treatment of EGPA in the US is available now. In recognition of the fact that US consumers are increasingly being asked by their insurers to take on more cost sharing, making affordability a concern for some patients, GSK has various patient assistance programmes available for those who be suitable.