BioSpectrum
the business of Bio & Health Sciences

Tezepelumab gets breakthrough therapy label to treat severe asthma

07 September 2018 | News

The Breakthrough Therapy Designation is supported by the tezepelumab Phase 2b PATHWAY data

Amgen and AstraZeneca announced that the U.S. Food and Drug Administration (FDA) have granted Breakthrough Therapy Designation for tezepelumab in patients with severe asthma without an eosinophilic phenotype.

A Breakthrough Therapy Designation is designed to expedite the development and regulatory review of medicines that are intended to treat a serious condition and that have shown encouraging early clinical results which may demonstrate substantial improvement on a clinically-significant endpoint over available medicines.

The Breakthrough Therapy Designation is supported by the tezepelumab Phase 2b PATHWAY data. The trial showed a significant reduction in the annual asthma exacerbation rate compared with placebo in a broad population of severe asthma patients independent of baseline blood eosinophil count or other type 2 (T2) inflammatory biomarkers.

Currently available biologic therapies only target T2 driven inflammation. Tezepelumab is a potential first-in-class new medicine that blocks thymic stromal lymphopoietin (TSLP), an upstream modulator of multiple inflammatory pathways.

"The Phase 2b PATHWAY trial data demonstrated tezepelumab's promise as a novel therapeutic option for a broad population of patients with severe asthma, including those ineligible for currently approved biologic therapies," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "The Breakthrough Designation will give us the opportunity to work closely with the FDA to bring tezepelumab to patients as quickly as possible."

Tezepelumab is currently in development in the Phase 3 PATHFINDER clinical trial program.