GlobalData»

New clinical data will support the use of a biosimilar treatment for Crohn's disease (CD), and lead to a boost in biosimilar market value, according to GlobalData , a leading data and analytics company.

In February 2018, 12-month data from the Personalized Anti-TNF therapy in Crohn's disease Study (PANTS) was presented at the 13th Congress of the European Crohn's and Colitis Organization (ECCO). The highly anticipated results demonstrated that Celltrion's CT-P13 (infliximab biosimilar) is comparable to its reference, Johnson and Johnson's Remicade (infliximab), as well as AbbVie's Humira (adalimumab).

Lakshmi Dharmarajan, Associate Director of Immunology at GlobalData , comments: "Given the dearth of head-to-head trial data, this is expected to bolster the use of biosimilars, and lead to cost-effective treatment strategies for patients with CD."

Conducted in the UK, PANTS is a three-year prospective study that assessed 1,601 patients with active CD who had received no prior treatment with any anti-tumor necrosis factor drugs. At the end of the 12-month study period, the remission rates were 40%, 40% and 34% for the Remicade, infliximab biosimilar, and Humira groups, respectively, while the immunogenicity rates were 26%, 28% and 11%.

Dharmarajan continues: "Many key opinion leaders interviewed by GlobalData believe that biosimilars are as safe and effective as the branded biologics, but have emphasized the need for additional clinical data. Therefore, the findings from PANTS will support the use of infliximab biosimilars over the originator brands."

Considering the next steps for promoting biosimilar use in the CD market, real-world evidence supporting the switching of the originators to the biosimilars would be essential. According to key opinion leaders, the current use of infliximab biosimilars is mostly restricted to infliximab-naïve patients; the PANTS study also focuses on this patient population. The interviewed gastroenterologists have expressed reluctance in switching a patient who is stable on Remicade to the biosimilar infliximab, due to concerns of the psychological impact on the patient, a situation similar to the use of generics.

Dharmarajan concludes: "Consequently, future clinical trials as well as real-world switching studies demonstrating the continued safety and efficacy of biosimilar use would go a long way in entrenching these cost-effective agents firmly into the CD pharmaceutical armamentarium. This in turn will help drive the biosimilar market for the disease, which was estimated to be worth $32.6m across the seven major markets (7MM*) in 2016, and is expected to grow to $1.4 billion in 2026, at a compound annual growth rate of 45.2%"

* 7MM: US, France, Germany, Italy, Spain, UK, and Japan