Eculizumab-Aagh Receives FDA Approval as Biosimilar to Soliris

Eculizumab-aagh does not have an interchangeable designation, though that could be updated in the future.

The FDA has approved the Biologics License Application for eculizumab-aagh (Samsung Bioepis; Epysqli) as a biosimilar to eculizumab (Alexion Pharmaceuticals; Soliris) to treat patients with paroxysmal nocturnal hemoglobinuria (PNS) and atypical hemolytic uremic syndrome (aHUS), according to a news release from Samsung Bioepis.[1]

This approval was based on a combination of evidence which demonstrated that eculizumab-aagh not only had equivalence and comparability to eculizumab regarding pharmacodynamics (PDs), but also in the clinical sense, having equivalent efficacy and safety between them.[1]

“The FDA approval of Epysqli as a biosimilar to Soliris marks an important milestone for PNH and aHUS communities since biosimilars have a potential to positively impact patients and health care systems by reducing health care costs and improving access to treatments,” Christopher Hansung Ko, president and CEO of Samsung Bioepis, said in the news release.[1]

Previously, the FDA had approved eculizumab-aeeb (Bkemv; Amgen) as an interchangeable biosimilar to eculizumab for the treatment of PNS and aHUS.[2] Eculizumab-aagh does not have an interchangeable designation, though that could be updated in the future.

In a clinical trial (NCT03722329), pharmacokinetics, safety, tolerability, and immunogenicity of eculizumab-aagh – referred to as SB12 – compared to both European Union- and United States-sourced eculizumab was evaluated. Lee et al. found that the 3 drugs “showed comparable pharmacodynamics, safety, and immunogenicity profiles.[3]

Another trial (NCT04058158) centered on the clinical efficacy comparison between eculizumab-aagh and the EU version of eculizumab, finding that by meeting the primary end points – reduction in haemolysis and time-adjusted area under the effect curve of lactate dehydrogenase – the proposed biosimilar demonstrated “equivalent clinical efficacy.”[4]

Eculizumab, a monoclonal antibody and anti-C5 complement inhibitor, is a common, established treatment for PNH and aHUS. The diseases are rare, with prevalence in the US estimated at approximately 50,000 for PNH and 5000 for aHUS.[1]

There are several barriers to more effective treatment with eculizumab. It has been found that 70% of patients treated with eculizumab are not dosed according to instructions on the label, and that two-thirds of patients discontinue the drug within an average of 1.5 years, which could be attributed to the high treatment cost.[4]

An additional biosimilar approved for the treatment of PNH and aHUS could relieve the financial burden on patients and open up treatment to more individuals.

“Our mission has been and always will be improving the lives of patients by providing quality-assured, safe, and effective biologic medicines, and our work to fulfill this mission is expanding into rare disease

areas where patients continue to suffer from limited access to life-enhancing medicines," Ko concluded.[1]

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