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US FDA approves first interchangeable biosimilar for two rare diseases

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The US Food and Drug Administration (FDA) has approved Amgen's Bkemv (eculizumab-aeeb) as the first interchangeable biosimilar to Soliris (eculizumab) to treat certain rare diseases. Bkemv is approved for the following treatment indications, which are also currently approved for Soliris:

- the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis; and
- the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

Bkemv is a monoclonal antibody that binds to the complement C5 protein and inhibits activation of the complement system, a part of the body's immune system. This binding prevents the breakdown of red blood cells in the bloodstream (intravascular hemolysis) in patients with PNH and aHUS.

As an interchangeable biosimilar, Bkemv is highly similar with no clinically meaningful differences to Soliris. Bkemv has the same safety warnings and is expected to have the same adverse reactions as Soliris.

Bkemv is available only through a restricted programme called the Bkemv Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety programme that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

Bkemv is the 53rd approved biosimilar in the US. The FDA has approved 13 of these as interchangeable biosimilars.