US FDA approves Amgen's biosimilar to AstraZeneca's rare blood disorder treatment

The approval comes with a black-box warning about the risk of serious infections caused by a bacteria called neisseria meningitidis.

London: The U.S. Food and Drug Administration approved on Tuesday Amgen's Bkemv, the first biosimilar to AstraZeneca's rare blood disorder treatment Soliris.

Amgen's drug will be marketed under the name Bkemv. Biosimilars are close copies of complex biological drugs.

The approval comes with a black-box warning about the risk of serious infections caused by a bacteria called neisseria meningitidis.

In 2022, the company said that Bkemv met the main goal of a late stage

Bkemv is approved to treat a rare blood disorder caused when the le immune system attacks and damages red blood cells and platelets.

AstraZeneca acquired the intravenous injection, Soliris, through a $39 billion buyout of Alexion Pharmaceuticals in 2020.

News Source:

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