UK regulator suspends rare-disease drug Tavneos for new patients over unreliable data

Sold as Avacopan Vifor in Britain by CSL Vifor, the drug is used with other medicines to treat severe autoimmune diseases that cause inflammation in small blood vessels and can damage the kidneys and lungs.

London: Britain's medicines regulator on Tuesday suspended the use and sale of Amgen's rare-disease drug Tavneos to new patients, saying the main study supporting its approval was unreliable.

Sold as Avacopan Vifor in Britain by CSL Vifor, the drug is used with other medicines to treat severe autoimmune diseases that cause inflammation in small blood vessels and can damage the kidneys and lungs.

The Medicines and Healthcare products Regulatory Agency said unreliable data from the main trial meant the study could no longer prove the drug worked or that its benefits outweighed the risks. The regulator plans to revoke UK approval for the drug on March 1, 2027.

Patients already receiving the drug can continue for six months, while doctors consider alternatives, the regulator said, adding that it has advised patients not to stop treatment without consulting a specialist.

Tavneos was developed by ChemoCentryx, which Amgen acquired for $3.7 billion in 2022. Amgen holds the U.S. rights, while CSL Vifor holds commercial rights in selected markets outside the U.S., including Britain.

"We disagree with the MHRA's decision to withdraw Tavneos from the UK market and are deeply concerned about the impact this decision may have on rare-disease patients," an Amgen spokesperson told Reuters.

Amgen said the regulator did not adequately consider evidence from clinical trials and more than 20 published real-world studies supporting the drug.

The European Commission revoked Tavneos' approval in August after regulators found key trial data to be unreliable.

The U.S. FDA has also proposed withdrawing the drug, citing unproven effectiveness and false statements in the original application. The FDA has also linked Tavneos to 76 cases of serious liver injury, including eight deaths.

Amgen is challenging the proposed U.S. withdrawal and has submitted more than 70 studies involving over 2,200 patients.

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