UKIVAS Statement on Avacopan 1st May 2026

This is short statement to share the available information we have in relation to the recent FDA and EMA statements on Avacopan, and how this may affect patients and clinicians in the UK.

This week, the FDA issued a formal proposal to withdraw approval for Tavneos (Avacopan) in the USA. Avacopan remains on the market at present unless the company decides to remove the drug or the FDA commissioner mandates its removal. In the meanwhile, the FDA suggests that health-care professionals discuss Avacopan and other available treatments with their patients to decide whether to use or continue to use Avacopan while a final decision is being made about the drug's marketing status.

In January this year, the EMA's human medicines committee (CHMP) started a review of Tavneos (Avacopan), following emerging information that raised questions regarding the data integrity of the Advocate study, which was the main study supporting the medicine's marketing authorisation in the European Union. We understand the EMA may report in the next few months.

In the UK, there have been no statements from the MHRA that we are currently aware of.

The FDA had also previously released a statement that highlighted safety concerns about cases of serious drug-induced liver injury (DILI) associated with Avacopan. Some cases involved vanishing bile duct syndrome (VBDS), which is characterized by progressive destruction and disappearance of the bile ducts in the liver. Hepatotoxicity is a serious adverse reaction that was previously noted in pre-clinical trials. For this reason, close blood monitoring is now recommended for all patients.

Is there a patient summary?

Yes, the patient group Vasculitis International have created a very helpful summary that is also being shared via Vasculitis UK.

Links:

https://www.fda.gov/drugs/drug-alerts-and-statements/cder-proposes-withdraw-approval-tavneos

https://www.fda.gov/drugs/drug-safety-communications/fda-identifies-cases-serious-liver-injury-patients-taking-tavneos-avacopan-severe-active-anti

https://www.ema.europa.eu/en/news/ema-starts-review-tavneos-medicine-rare-autoimmune-diseases-gpa-mpa

Patient information:

https://www.vasculitisint.com/update-tavneos-april-29th-2026/

https://www.vasculitis.org.uk/news/tavneos-avacopan-update

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