16 July 2026

Tavneos (avacopan) – recommendation for revocation of the marketing authorisation in the EU due to unfavourable benefit-risk balance

Dear Healthcare Professional,

Vifor Fresenius Medical Care Renal Pharma France, in agreement with the European Medicines Agency (EMA) and the Malta Medicines Authority, would like to inform you of the following:

Summary

- **Due to data integrity issues, the single pivotal phase 3 ADVOCATE study supporting the marketing authorisation of Tavneos can no longer be relied upon to demonstrate efficacy.**
- **Therefore, the benefit-risk balance of Tavneos can no longer be considered favourable and its marketing authorisation in the EU has been recommended for revocation.**
- **No new patients should be started on Tavneos.**
- **Prescribers should contact patients currently receiving Tavneos to discontinue treatment and discuss alternative treatment options.**
- **Since additional cases of drug-induced liver injury (DILI) and vanishing bile duct syndrome (VBDS) were reported, including cases with fatal outcome, requirements for liver function monitoring have been reinforced. Until treatment with Tavneos is discontinued, liver function must be monitored:**
    - **for patients in the first 3 months of treatment: at least every 2 weeks.**
    - **for patients already treated for more than 3 months: every 4 weeks until 6 months of treatment and as clinically indicated thereafter.**
- **Treatment must be immediately discontinued if VBDS is suspected.**

Background information

Tavneos (avacopan), in combination with a rituximab or cyclophosphamide regimen, was authorised in the EU in January 2022 for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).

The initial authorization of Tavneos was based on the results from the pivotal phase 3, randomised, double-blind, active-controlled, study (ADVOCATE). In the ADVOCATE study, Tavneos was compared with prednisone taper, both in addition to standard treatment (either rituximab or a regimen consisting of cyclophosphamide followed by azathioprine). Based on data from this study, Tavneos was found to be non-inferior to high-dose corticosteroids in inducing remission in patients with GPA or MPA and was associated with higher sustained remission rates.

EMA's human medicines committee (CHMP) has concluded a review of Tavneos, taking into account new information that raised questions regarding the data integrity of the ADVOCATE study, in the context of all available data.

CHMP concluded that, due to the handling of the database for the ADVOCATE study prior to the regulatory approval of Tavneos, the results of this study cannot be relied upon for the demonstration of efficacy. Supportive post-marketing data were not considered sufficient to demonstrate the efficacy of Tavneos. Overall, data to demonstrate a substantial benefit to outweigh the known serious safety risks of Tavneos is no longer available.

CHMP also noted the increased hepatic safety concerns. As part of the latest periodic safety update, the EMA's safety committee (PRAC) reviewed all available hepatotoxicity data, including additional cases of drug-induced liver injury (DILI) and vanishing bile duct syndrome (VBDS), including cases with fatal outcome. As an outcome, the requirements for liver monitoring have been reinforced for patients treated with Tavneos[1].

Therefore, the CHMP concluded that the benefit-risk balance of Tavneos is no longer favourable and recommended the revocation of the marketing authorisation in the EU. If this recommendation is confirmed by the European Commission, Tavneos will no longer be authorised in the EU.

No new patients should be started on Tavneos outside of a clinical trial. Physicians should contact patients currently on treatment to discontinue treatment and discuss alternative options with them.

Call for reporting

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Malta Medicines Authority ADR reporting form available online at: http://medicinesauthority.gov.mt/adrportal and sent to Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt

Any suspected adverse reactions may also be reported to Vifor Fresenius Medical Care Renal Pharma France at: adverse.events@csl.com

Company contact point

If you have any questions, or if you require any further information, please contact the medical information service of the Marketing Authorisation Holder at: cee_mea_medinfo@viforpharma.com

[1] For additional information, please refer to Meeting highlights from the Pharmacovigilance Risk Assessment Committee [PRAC] 8-11 June 2026;
URL: https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-8-11-june-2026