30 January 2026
EMA/18986/2026

EMA starts review of Tavneos, a medicine for rare autoimmune diseases GPA and MPA

Review prompted by questions regarding data integrity of main study

EMA's human medicines committee (CHMP) has started a review of Tavneos (avacopan), following emerging information that raises questions regarding the data integrity of the Advocate study, which was the main study supporting the medicine's marketing authorisation in the European Union.

Tavneos was authorised in the EU in January 2022 for treating adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), two rare inflammatory conditions of the blood vessels.

In the Advocate study, which included 331 patients with GPA or MPA, Tavneos was compared with high-dose corticosteroids (medicines used to treat inflammatory diseases), 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 at least as effective as high-dose corticosteroids in inducing remission in patients with GPA or MPA and to lead to better long-term remission rates.

The concerns relate to how the data for the Advocate study was handled before Tavneos was authorised, which may have impacted the findings on the medicine's effectiveness.

EMA will now review all available data to assess whether this emerging information has an impact on the balance of benefits and risks of Tavneos. The Agency will then issue a recommendation on whether the marketing authorisation in the EU should be maintained, amended, suspended or revoked.

More about the medicine

Tavneos is a medicine used to treat adults with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), which are inflammatory conditions of the blood vessels. Tavneos is used as part of a combined treatment also including the medicines rituximab or cyclophosphamide. Tavneos contains the active substance avacopan.

More information on Tavneos is available on the medicine's page on the EMA website.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

More about the procedure

The review of Tavneos has been initiated at the request of the Europan Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.