



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/CHMP/624375/2021  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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# Tavneos avacopan

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tavneos<sup>2</sup>, intended, in combination with a rituximab or cyclophosphamide regimen, for the treatment of adult patients with severe, active granulomatosis with polyangiitis or microscopic polyangiitis.

The applicant for this medicinal product is Vifor Fresenius Medical Care Renal Pharma France.

Tavneos will be available as 10 mg hard capsules. The active substance of Tavneos is avacopan, a selective antagonist of the human complement 5a (C5a) receptor (ATC code: not yet assigned). By blocking the C5a receptor, avacopan reduces the pro-inflammatory effects of C5a, including neutrophil activation, migration, and adherence to vascular endothelial surfaces.

The benefits of Tavneos are mainly related to patients achieving disease remission at Week 26 and sustained remission at week 52. Remission was defined as a Birmingham Vasculitis Activity Score of 0 and not taking glucocorticoids for treatment of ANCA-associated vasculitis within four weeks prior to week 26; and sustained remission indicated subjects in remission at week 26 and uninterrupted up to week 52. Avacopan was used as combination treatment with cyclophosphamide followed by combination of avacopan with azathioprine or mycophenolate or in combination with rituximab followed by avacopan monotherapy; and with glucocorticoids as needed.

The most common side effects included upper respiratory tract infection, nasopharyngitis, headache, nausea, diarrhoea, vomiting, increased liver function tests, decreased white blood cell count.

The full indication is:

Tavneos, in combination with a rituximab or cyclophosphamide regimen, is indicated for the treatment of adult patients with severe, active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA).

Treatment with Tavneos should be initiated and monitored by healthcare professionals experienced in the

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained



diagnosis and treatment of GPA or MPA.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.