For Immediate Release

ASX Announcement

29 June 2026
Melbourne, Australia

Update on TAVNEOS® (avacopan) in the European Union

CSL Limited (ASX:CSL; USOTC:CSLLY) today provides an update regarding TAVNEOS® (avacopan), an in-licensed therapy sold by CSL Vifor affiliates under licence in European Union (EU) and European Economic Area (EEA) markets.

On 26 June 2026, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) issued an opinion recommending the revocation of the EU marketing authorisation for TAVNEOS. This opinion follows CHMP's review under Article 20 of the handling of data in the pivotal Phase 3 ADVOCATE clinical trial supporting the product's approval.

TAVNEOS is indicated for the treatment of adults with severe, active anti neutrophil cytoplasmic antibody (ANCA) associated vasculitis, in combination with standard therapies.

TAVNEOS was developed by ChemoCentryx and is commercialised outside the US and in selected countries by CSL, its affiliates and partners pursuant to a 2016 collaboration and license agreement between Vifor Fresenius Medical Care Renal Pharma Ltd (VFMCRP) and ChemoCentryx. Amgen acquired ChemoCentryx in 2022. The ADVOCATE trial was conducted by ChemoCentryx prior to CSL's acquisition of Vifor Pharma.

The European Commission (EC) will review the CHMP opinion and issue a final decision in due course.

In light of the CHMP opinion and pending the EC decision, CSL expects to cease new patient initiation in the EU and EEA markets, consistent with regulatory guidance.

Dr Bill Mezzanotte, CSL's Head of Research & Development said:

> "While we are disappointed in the outcome of the Article 20 procedure, we will respect the regulatory process and are committed to implementing it in full. We recognise this is a difficult moment for the community, as TAVNEOS has played an important role for patients living with ANCA-associated vasculitis, a life-threatening disease with limited treatment options. VFMCRP and CSL remain focused on bringing innovative treatment options to patients living with rare diseases.
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> "Patient care remains our highest priority, and we are working closely with regulatory authorities, healthcare professionals and patient organisations to ensure a compliant and appropriate treatment transition, along with ongoing support for patients."

Sales revenue from TAVNEOS for FY26 is expected to be approximately $145m. Further detail, including impairment of TAVNEOS intellectual property, will be provided as part of CSL's 2026 Full Year results in August 2026. This announcement does not change the estimated impairment provided to investors on 11 May 2026.

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About ANCA-associated vasculitis (GPA/MPA)

Anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) is a life-threatening disease where the body's immune system mistakenly attacks its own blood vessels. This causes inflammation and irreversible organ damage, most frequently to the kidneys, and lungs, and requires treatment to manage the disease. The two main forms are granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). Both disease and treatment burden markedly diminish quality of life for affected patients. The unmet medical need remains high as people living with AAV face significant risk of complications, driven both by the disease and treatment-related adverse effects, including from high dose and/or long-term use of glucocorticoids.

About TAVNEOS® (avacopan)

TAVNEOS® (avacopan) is an orally administered small molecule that is a selective inhibitor of the complement C5a receptor C5aR1. By blocking the receptor (the C5aR) for the pro-inflammatory complement system fragment, C5a on inflammatory cells such as blood neutrophils, TAVNEOS inhibits the ability of those cells to do damage in response to C5a activation, which is known to be the driver of inflammation. Moreover, the selective inhibition by TAVNEOS of only the C5aR1 leaves other immune system responses functioning normally.