June 29, 2026

Kissei Pharmaceutical Co., Ltd.
(Code 4547, Tokyo Stock Exchange Prime Market)

Announcement for the Opnion by European Authorities on TAVNEOS

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano Prefecture; Chairman and CEO: Mutsuo Kanzawa; "Kissei") announced the opinion by European authorities regarding concerns over the integrity of data from the international Phase III clinical trial of TAVNEOS (generic name: avacopan), a treatment for microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA), which are designated as intractable diseases.

TAVNEOS was developed by ChemoCentryx and is commercialised outside the US and in selected countries by CSL, its affiliates and partners pursuant to a collaboration and license agreement between Vifor Fresenius Medical Care Renal Pharma Ltd. and ChemoCentryx. Vifor Fresenius Medical Care Renal Pharma Ltd. has subsequently sublicensed the rights in Japan to Kissei[1]. Amgen acquired ChemoCentryx in 2022.

On January 30, 2026, the European Medicines Agency (EMA) initiated a review by the Committee for Medicinal Products for Human Use (CHMP) because concerns arose regarding data integrity in the multinational Phase III clinical trial. On June 26, 2026, the CHMP recommended revoking the marketing authorization in the European Union (EU) for TAVNEOS, stating that it had not been demonstrated that the benefits outweigh the risks. The CHMP's opinion has been submitted to the European Commission (EC), and a final decision by the EC is expected later. Please check the EMA website for details[2].

Kissei will continue the discussions regarding the appropriate measures in Japan with the Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency (PMDA).The impact of this matter on Kissei’s business performance is currently under review. If it becomes clear that there will be an impact on our performance, we will promptly disclose the information.

1 News Release：June 9, 2017
Exclusive License Agreement for Avacopan, a selective inhibitor of the Complement C5a Receptor, for Rare Kidney Diseases, in Japan

2 EMA recommends revoking marketing authorisation for Tavneos：26 June, 2026
＜EMA recommends revoking marketing authorisation for Tavneos | European Medicines Agency (EMA)＞

＜Reference＞

About ANCA-associated Vasculitis (AAV)

It is an intractable inflammatory disease characterized by necrotizing inflammation of small blood vessels with listtle to no deposition of immune complexes and a high ANCA positivity rate. It can affect various organs, including the kidneys, lungs, and nervous system. MPA and GPA, classified under ANCA-associated vasculitis (AAV), are designated as intractable diseases by the Ministry of Health, Labour and Welfare, and can lead to serious health issues, especially when they become severe.

About TAVNEOS (generic name: Avacopan)

TAVNEOS is a treatment for rare diseases in the renal field and others, developed by ChemoCentryx, Inc. (USA). This drug is an orally administrable small molecule compound that antagonizes the C5a receptor present on white blood cells such as neutrophils. By inhibiting the migration of white blood cells and the induction of adhesion molecules, it provides a significant and effective therapeutic effect against MPA and GPA.