



May 15, 2026

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

Regarding the Proper Use of TAVNEOS

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano Prefecture; Chairman and CEO: Mutsuo Kanzawa, "Kissei") announces the initiation of information dissemination activities aimed at encouraging healthcare professionals to exercise careful administration of TAVNEOS (generic name: Avacopan), which has been exclusively licensed for development and commercialization in Japan from Vifor Fresenius Medical Care Renal Pharma Ltd. (now CSL Vifor) in June 2017, and has been marketed in Japan since June 2022 for the treatment of microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA)*.

On March 31, 2026, the U.S. Food and Drug Administration (FDA) issued a notice warning patients and healthcare professionals about severe drug-induced liver injury identified in patients taking this drug. Furthermore, the Center for Drug Evaluation and Research (CDER) of FDA announced on April 27, 2026, that it proposed the withdrawal of its approval in the United States, asserting that there is new information indicating lack of substantial evidence of effectiveness for the drug and that ChemoCentryx's application that resulted in FDA approval contained untrue statements of material facts. In addition, the European Medicines Agency (EMA) announced on January 30, 2026, that it has initiated a review by the Committee for Medicinal Products for Human Use (CHMP) due to concerns regarding the integrity of data from the Phase III clinical trial study.

Currently, Kissei is gathering detailed information from the U.S. and Europe, providing necessary information to the Pharmaceuticals and Medical Devices Agency (PMDA), and engaging in discussions also with the Ministry of Health, Labour and Welfare. While the approval of this drug in Japan remains in effect, Kissei has begun providing information to healthcare professionals, urging them to refrain from using this drug for new patients and to carefully assess the continuation of treatment for existing patients, explaining the risks of liver dysfunction and alternative treatments to ensure patient safety.

Healthcare professionals are encouraged to visit Kissei's "Healthcare Professionals Site" (https://med.kissei.co.jp/product/TAVNEOS_Capsules_10mg.html) for information related to the proposal to withdraw the U.S. approval and appropriate usage of this drug. Patients currently taking this drug should not independently decide on the continuation of treatment and are

advised to consult with their treating physician.

The sales revenue of this product for the fiscal year ending March 2026 was 11.524 billion yen. The impact of this matter on Kissei's business performance is currently under review.

* News Release: June 6, 2022

Launch of TAVNEOS® Capsules 10mg, a selective Complement C5a Receptor Antagonist

<References>

About TAVNEOS (generic name: Avacopan)

TAVNEOS, created by ChemoCentryx, Inc. (U.S.), is a treatment for rare kidney diseases. It is an orally administered small-molecule agent that antagonizes the C5a receptor on leukocytes, including neutrophils, preventing their migration and the induction of adhesion molecules, thereby exerting therapeutic effects. The indications for this drug, microscopic polyangiitis and granulomatosis with polyangiitis, are designated as intractable inflammatory diseases by the Ministry of Health, Labour and Welfare in Japan and often present with necrotizing glomerulonephritis.

ChemoCentryx has licensed the rights to this drug to Vifor Fresenius Medical Care Renal Pharma Ltd. for all countries outside the U.S., and Vifor Fresenius Medical Care Renal Pharma Ltd. has sublicensed the rights in Japan to Kissei. Currently, ChemoCentryx has been acquired by Amgen Inc., and Vifor Fresenius Medical Care Renal Pharma Ltd. has been acquired by CSL Limited.

In the U.S., TAVNEOS is marketed by Amgen Inc., and in Europe, it is marketed by CSL Vifor. For more details on Amgen Inc. and CSL Vifor, please refer to their respective websites.

Amgen Inc.: <https://wwwext.amgen.com/amgen-worldwide>

CSL Vifor: <https://www.csl.com/we-are-csl/our-businesses-and-products/csl-vifor>