



May 21, 2026

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

Raising Awareness for Safe Use of TAVNEOS

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano Prefecture; Chairman and CEO: Mutsuo Kanzawa; "Kissei") announced today that, following instructions from the Ministry of Health, Labour and Welfare based on legal regulations, it has revised the package insert in Japan for "TAVNEOS" (generic name: avacopan), a treatment for the designated intractable diseases, microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA), regarding serious hepatic dysfunction. Additionally, Kissei has issued a Rapid Safety Communication (Blue Letter) to inform and alert healthcare professionals about this matter.

1. The contents of the revision of the package insert
 - 1) In the precautions for use section, it is noted as a warning that serious liver dysfunction, including vanishing bile duct syndrome, may occur, and there have been reported cases of death. Therefore, it is advised to conduct regular liver function tests before and during administration, closely monitor the patient's condition, and take appropriate measures.
 - 2) In the precautions for use section, it is noted as the important precautions for use that liver dysfunction often occurs within the first three months of administration. Additionally, it includes information on the timing of liver function tests and observations that require appropriate intervention.
2. Summary of the Rapid Safety Communication

The contents outlined in the revised package insert regarding precautions for the early detection and prevention of worsening liver dysfunction in both new and continuing patients are included.

Kissei requested healthcare professionals on May 15, 2026, to ensure patient safety by refraining from using TAVNEOS for new patients for the time being, and to carefully assess the necessity of continued administration for patients who were currently undergoing treatment¹. In light of today's revision of the package insert, Kissei requests healthcare professionals to ensure that new patients undergo liver function tests especially after starting administration, and that patients on continued administration have regular liver function tests, to facilitate the early detection and prevention of worsening liver dysfunction.

To all healthcare professionals, when using TAVNEOS for new and continuing patients, please review the Rapid Safety Communication published on the Kissei's website and the package insert to ensure the proper use of TAVNEOS.²

Additionally, for patients taking TAVNEOS, please do not stop taking the medication on your own judgment and promptly consult a physician or pharmacist if there are any changes in your condition.

Furthermore, Kissei has established a "Drug Consultation Center" for healthcare professionals and patients. Please contact us if you have any questions. ³

We are currently examining the impact of this matter on our company's performance. If it becomes clear that there will be an impact on our performance, we will promptly disclose the information.

1 News Release: May 15, 2026
Regarding the Proper Use of TAVNEOS

2 Kissei Pharmaceutical Corporate Website
URL: <https://www.kissei.co.jp/>

A shortcut to access the Rapid Safety Communication for this medication is provided on the top page.

3 Contact Information: Kissei Pharmaceutical Co., Ltd. Drug Consultation Center

Toll-Free Number: 0120-007-622

Reception Hours: 9:00 AM to 5:40 PM

(Excluding weekends, public holidays, and company holidays)

Outside of these hours, inquiries are accepted via voicemail.

<Reference>

About ANCA-associated Vasculitis (AAV)

It is an intractable inflammatory disease characterized by necrotizing inflammation of small blood vessels with little 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.

ChemoCentryx has granted rights for certain countries outside of the United States to Vifor Fresenius Medical Care Renal Pharma Ltd. Vifor Fresenius Medical Care Renal Pharma Ltd.

has subsequently sublicensed the rights in Japan to Kissei.

In 2022, ChemoCentryx was acquired by Amgen Inc. TAVNEOS is marketed in the United States by Amgen and in Europe by Vifor Fresenius Medical Care Renal Pharma France.