



October 22, 2026

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

Announcement for the Results Report by the Council of Pharmaceutical Affairs (Medical Product Second Section) on TAVNEOS

Kissei Pharmaceutical Co., Ltd. (Head Office: Matsumoto City, Nagano Prefecture; Chairman and CEO: Mutsuo Kanzawa; "Kissei") announced the results report by the Council of Pharmaceutical Affairs (Medical Product Second Section) on TAVNEOS (generic name: avacopan), a treatment for microscopic polyangiitis (MPA) and granulomatosis with polyangiitis (GPA), which are designated as intractable diseases.

Regarding TAVNEOS, on May 15, 2026, Kissei commenced information dissemination activities urging healthcare professionals to exercise caution in administering the medication. Furthermore, on May 21, 2026, Kissei revised the package insert in Japan for TAVNEOS regarding serious hepatic dysfunction. Additionally, Kissei has issued a Rapid Safety Communication (Blue Letter) to inform and alert healthcare professionals about this matter. Furthermore, Kissei received an administrative order from the Minister of Health, Labour and Welfare (MHLW). Additionally, Kissei received an order from the MHLW to verify the facts concerning the reliability of data from an international Phase III clinical trial—which has been a subject of concern in Western countries—as well as the safety of this product; we have since submitted our response to this order.

At the meeting of the Council of Pharmaceutical Affairs (Medical Product Second Section) held yesterday (October 21, 2026), the Pharmaceuticals and Medical Devices Agency (PMDA) reported the findings of its review regarding responses submitted in accordance with an official request for information. The review indicated potential issues with the reliability of the data submitted during the drug approval process, making it difficult to conclude that the therapeutic benefits of the product outweigh its risks. At the same time, given that the target condition is a serious, rare disease, any changes to the treatment of patients currently receiving the drug must be determined on an individual basis, taking into account each patient's clinical status and the availability of alternative treatment options. In light of this, the MHLW has requested that medical institutions and other relevant facilities adopt the following measures regarding the administration of this drug for the time being.

1. Do not initiate treatment with this drug in new patients.
2. For patients currently receiving this drug, consider discontinuing treatment or switching to an alternative therapy. When deciding whether to discontinue or switch, evaluate each patient's clinical condition, treatment efficacy, available alternative treatment options, and the potential impact of changing the treatment regimen.

3. If the use of this drug is continued—for instance, during the period leading up to a switch to an alternative therapy—ensure that it is used appropriately in accordance with the safety alert (Blue Letter) issued on May 21, 2026.

Kissei will promptly communicate this response policy to medical institutions and other relevant entities. 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 News Release: May 21, 2026
Raising Awareness for Safe Use of TAVNEOS
- 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. TAVNEOS has received manufacturing and marketing approval in Japan for the treatment of MPA and GPA; however, the reliability of the clinical trial data that served as the basis for the approval and the benefit-risk profile of this drug are currently under review by the regulatory authorities. At this time, TAVNEOS is available for patients living with severe active GPA/MPA in the United States.