Important Safety Information on PRTAVNEOS® (avacopan) and Health Canada's Review of Data Integrity Concerns

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Audience
Healthcare professionals involved in the treatment and management of patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis, including rheumatologists, nephrologists, pulmonologists, internal medicine physicians, family physicians, nurse practitioners, and pharmacists.

Key messages

- **Health Canada has identified significant concerns about the data that supported the authorization of TAVNEOS (avacopan).**
- **These concerns raise questions about the efficacy of TAVNEOS.**
- **Pending the outcome of Health Canada's review of these concerns, healthcare professionals are advised to:**
  - **NOT initiate treatment with TAVNEOS in new patients.**
  - **Contact and monitor patients currently receiving TAVNEOS and assess whether continued treatment remains appropriate.**

What is the issue?
Health Canada is reviewing significant concerns regarding the data integrity of the pivotal ADVOCATE trial, which served as the primary efficacy study supporting the authorization of TAVNEOS (avacopan).

Products affected
TAVNEOS (avacopan) capsules, 10 mg

Background information
TAVNEOS (avacopan) is indicated for the adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard background therapy including glucocorticoids. TAVNEOS is not indicated for use as monotherapy and does not eliminate glucocorticoid use.

The authorization of TAVNEOS in Canada (April 2022) was supported primarily by

the pivotal Phase 3 ADVOCATE trial, sponsored by ChemoCentryx, which evaluated the use of avacopan in patients with GPA or MPA receiving standard therapy.

New information has raised significant concerns regarding the integrity of the clinical data from the ADVOCATE trial. The concerns relate to how the data for the ADVOCATE trial was handled before TAVNEOS was authorized, creating uncertainty about the reliability of the efficacy evidence supporting the product's benefit-risk profile.

Due to the data integrity concerns, the ADVOCATE trial publication was retracted by the *New England Journal of Medicin*e on June 29, 2026.

Health Canada is currently reviewing this information and assessing its impact on the authorization of TAVNEOS in Canada.

Information for consumers
TAVNEOS is used to treat adults with conditions known as severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis, which are rare autoimmune diseases that cause inflammation of blood vessels. They include granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). TAVNEOS is used along with other medicines to treat these conditions.

TAVNEOS was authorized in Canada after Health Canada reviewed the information available at the time, including the main clinical trial data used to support its use. Recently, new information has raised serious concerns about the reliability of that data, creating uncertainty about the evidence used to show how well TAVNEOS works. Health Canada is reviewing this information, together with the known risks of TAVNEOS, to determine whether its benefits continue to outweigh its risks.

Patients should not stop taking TAVNEOS without first speaking to their healthcare professional.

Patients currently taking TAVNEOS should contact their healthcare professional to discuss their treatment and whether another therapy may be appropriate.

Information for healthcare professionals
Pending the outcome of Health Canada's review of these concerns, healthcare professionals are advised to:

- NOT initiate treatment with TAVNEOS in new patients.
- Contact and monitor patients currently receiving TAVNEOS and assess whether continued treatment remains appropriate.

Action taken by Health Canada
Health Canada is communicating this important safety information to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system.

Report health or safety concerns
Managing marketed health product-related side effects depends on healthcare

professionals and consumers reporting them. Any case of serious or unexpected side effects in patients receiving TAVNEOS should be reported to Otsuka Canada Pharmaceutical Inc. or Health Canada.

Otsuka Canada Pharmaceutical Inc.
Address: 2250 Boul. Alfred Nobel, Suite 301 Saint-Laurent (Québec) H4S 2C9
Telephone (Toll free): 1-877-341-9245
Fax: 1-844-268-9110
Email: OCPI-AdverseEvents@otsuka-ca.com or OCPI-MedInfo@otsuka-ca.com

To correct your mailing address or fax number, contact Otsuka Canada Pharmaceutical Inc.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Pharmaceutical Drugs Directorate
E-mail: pharma_drug_enquiries-renseignements_medicaments_pharma@hc-sc.gc.ca
Telephone: 613-957-0368
Fax: 613-952-7756

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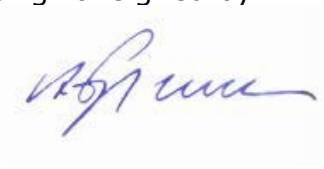

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