

YOU ARE CORDIALLY INVITED TO ATTEND A PRESENTATION TITLED:

Advances in the Treatment of ANCA-Associated Vasculitis

PRESENTED BY:

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DATE:

Friday, May 12th, 2023, 11:45am - 12:20 pm EST

LOCATION:

Founder's Room
InterContinental Hotel & Conference Center
9801 Carnegie Avenue
Cleveland, OH 44106

PLEASE RSVP TO:

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This program/event is developed and offered by Amgen. This is not an official program/event of the Cleveland Clinic.

INDICATION

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

Serious hypersensitivity to avacopan or to any of the excipients.

Please see Important Safety Information continued on the following page.



IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Hepatotoxicity: Serious cases of hepatic injury have been observed in patients taking TAVNEOS, including life-threatening events. Obtain liver test panel before initiating TAVNEOS, every 4 weeks after start of therapy for 6 months and as clinically indicated thereafter. Monitor patients closely for hepatic adverse reactions, and consider pausing or discontinuing treatment as clinically indicated (refer to section 5.1 of the Prescribing Information). TAVNEOS is not recommended for patients with active, untreated, and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis. Consider the risks and benefits before administering this drug to a patient with liver disease.

Serious Hypersensitivity Reactions: Cases of angioedema occurred in a clinical trial, including 1 serious event requiring hospitalization. Discontinue immediately if angioedema occurs and manage accordingly. TAVNEOS must not be readministered unless another cause has been established.

Hepatitis B Virus (HBV) Reactivation: Hepatitis B reactivation, including life-threatening hepatitis B, was observed in the clinical program. Screen patients for HBV. For patients with evidence of prior infection, consult with physicians with expertise in HBV and monitor during TAVNEOS therapy and for 6 months following. If patients develop HBV reactivation, immediately discontinue TAVNEOS and concomitant therapies associated with HBV reactivation, and consult with experts before resuming.

Serious Infections: Serious infections, including fatal infections, have been reported in patients receiving TAVNEOS. The most common serious infections reported in the TAVNEOS group were pneumonia and urinary tract infections. Avoid use of TAVNEOS in patients with active, serious infection, including localized infections. Consider the risks and benefits before initiating TAVNEOS in patients with chronic infection, at increased risk of infection, or who have been to places where certain infections are common.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 5\%$ of patients and higher in the TAVNEOS group vs. prednisone group) were nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia.

DRUG INTERACTIONS

Avoid coadministration of TAVNEOS with strong and moderate CYP3A4 enzyme inducers. Reduce TAVNEOS dose when coadministered with strong CYP3A4 enzyme inhibitors to 30 mg once daily. Monitor for adverse reactions and consider dose reduction of certain sensitive CYP3A4 substrates.

TAVNEOS is available as a 10 mg capsule.

Please see accompanying Full Prescribing Information and Medication Guide for TAVNEOS.

To report a suspected adverse event, call 1-833-828-6367. You may report to the FDA directly by visiting www.fda.gov/medwatch or calling 1-800-332-1088.

PhRMA guidance: Effective January 1, 2022, the PhRMA Code was revised to include certain new requirements for industry provided Speaker Programs. To comply with these new requirements, Amgen will no longer pay for or provide alcohol in connection with our Speaker Programs.

Amgen's COVID-19 speaker program risk mitigation guidance: To mitigate the risk of COVID-19 transmission and in accordance with CDC guidance, attendees are asked to follow the local social distance and safety guidance at all times. Individuals exhibiting signs and symptoms of COVID-19 infection should not attend.

Notice: This event is conducted in accordance with the PhRMA Code on Interaction with Healthcare Professionals and is limited to invited healthcare professionals. Attendance by guests or spouse is not appropriate. Government employees are subject to state and federal laws and ethics rules that may limit your ability to receive any gifts, including meals, from pharmaceutical companies. If you are a state or federal employee, it is your responsibility to seek guidance and prior approval from your employer or site ethics counselor to attend this event.

State Laws: To comply with law and Amgen policies, Amgen is unable to offer food and beverages to (1) individuals with prescribing authority in Vermont or Minnesota; or (2) individuals employed by prescribers in Vermont who support the provision of healthcare. Please confirm the value of the meal with your Amgen representative before accepting the meal. You have the opportunity to opt-out of the meal and/or purchase your own meal, if applicable. Please note that Amgen exercises diligence in reviewing the licensure of attendees and asks that you cooperate by disclosing all licensures in the sign-in/registration process. We appreciate your understanding and support.

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