YOU ARE CORDIALLY INVITED TO ATTEND
A PRESENTATION TITLED:

Achieving and Sustaining Remission in Severe Active ANCA-Associated Vasculitis: GPA and MPA

SPECIFIC TOPICS INCLUDE:

- Heterogeneous and multi-systemic presentation of severe active GPA and MPA
- Pathophysiologic pathways that can serve as targets for therapeutic intervention
- Results from the pivotal ADVOCATE study
- Identification of appropriate patients for TAVNEOS®

PRESENTED BY:

Robert Woodrick, MD
Northwestern University
Feinberg School of Medicine
Assistant Professor of Medicine

Speaker Bio: Dr. Woodrick is an associate professor at Northwestern University Division of Rheumatology. Dr Woodrick Attended medical school at the University of Illinois- Chicago and graduated with honors after graduating magna cum laude at Loyola University. He continued his "Chicago rounds", completing Internal Medicine Residency and Rheumatology Fellowship at Northwestern University Feinberg of Medicine and was awarded the Gerald Grumet Award for outstanding teaching as a senior resident by the intern class.

DATE:

Saturday, March 15, 2025 6:30 PM

LOCATION:

Nana's Restaurant
2514 University Drive
Durham NC 27701

PLEASE RSVP TO:

Michael Kenady
mkenady@amgen.com
919-696-8571

TAVNEOS (avacopan) is indicated as an 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 therapy including glucocorticoids. TAVNEOS does not eliminate glucocorticoid use.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Serious hypersensitivity to avacopan or to any of the excipients.

Please see additional Important Safety Information continued on the following page.

TAVNEOS® (avacopan)

IMPORTANT SAFETY INFORMATION (CONT'D)

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 (≥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 co-administration of TAVNEOS with strong and moderate CYP3A4 enzyme inducers. Reduce TAVNEOS dose when co-administered with strong CYP3A4 enzyme inhibitors to 30 mg once daily. Consider dose reduction of CYP3A4 substrates when co-administering TAVNEOS. Co-administration of avacopan and 40 mg simvastatin increases the systemic exposure of simvastatin. While taking TAVNEOS, limit simvastatin dosage to 10 mg daily (or 20 mg daily for patients who have previously tolerated simvastatin 80 mg daily for at least one year without evidence of muscle toxicity). Consult the concomitant CYP3A4 substrate product information when considering administration of such products together with TAVNEOS.

TAVNEOS is available as a 10 mg capsule.

Please see 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.

Disclosure by Amgen: Amgen reports payments and transfers of value made to healthcare professionals and other healthcare-related entities in accordance with federal and state laws, regulations and other transparency obligations. Any items of value provided by Amgen at this event (including the provision of meals and refreshments) may be subject to public disclosure. If you have questions regarding this matter please contact Amgen at 805-447-7422 or HCCSpendInquiry@amgen.com.

ANCA = anti-neutrophil cytoplasmic autoantibody; CDC = Centers for Disease Control and Prevention; COVID-19 = coronavirus disease 2019; GPA = granulomatosis with polyangiitis; MPA = microscopic polyangiitis; PhRMA = Pharmaceutical Research and Manufacturers of America.

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TAVNEOS® (avacopan)