The First Signs Matter:

Detecting and Treating Early Symptomatic Alzheimer's Disease

Gain knowledge that can help you take action in your own practice.

Learn about the anti-amyloid therapy Kisunla® (donanemab-azbt) and what you can do to detect and refer patients early when symptoms present.

We'll discuss:

- Why early detection of Alzheimer's Disease (AD) is critical
- A review of the phase III efficacy and safety data for Kisunla
- How to assess patients for AD
- Best practices for referring to a specialist

A question-and-answer session will follow the presentation.

Scan for more information

We look forward to you joining us!

TUESDAY, JULY 21, 2026

6:30 PM EST

RSVP

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Please RSVP by Tuesday, July 21, 2026.

Location

Venue
Paesano
3411 Washtenaw Ave
Ann Arbor, Michigan 48104

Speaker

Nader Warra, DO, BA

INDICATION

Kisunla is indicated for the treatment of Alzheimer's disease (AD). Treatment with Kisunla should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

IMPORTANT SAFETY INFORMATION FOR Kisunla® (donanemab-azbt)

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including Kisunla, can cause amyloid-related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events can occur. ARIA can be fatal. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with Kisunla.

ApoE ε4 Homozygotes: Patients treated with this class of medications, including Kisunla, who are apolipoprotein E ε4 (ApoE ε4) homozygotes (approximately 15% of Alzheimer's disease patients) have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, the risk of ARIA across genotypes and the implications of genetic testing results should be discussed with patients.

Consider the benefit for treating Alzheimer's disease and risk of ARIA when deciding to treat with Kisunla.

Kisunla is **contraindicated** in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients. Reactions have included anaphylaxis.

Please see additional Important Safety Information, including Boxed Warning regarding ARIA, on pages 2-3, and accompanying full Prescribing Information for Kisunla.

kisunla® (donanemab-azbt) injection for intravenous use 350mg/20mL

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Amyloid-Related Imaging Abnormalities (ARIA)

ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, can occur. ARIA can be fatal. When present, reported symptoms associated with ARIA may include, but are not limited to, headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

In Study 1, safety was assessed in patients who received Kisunla Dosing Regimen 1 (n=853) compared to those who received placebo (n=874). In Study 2, the effect of different dosing regimens of Kisunla on ARIA was assessed, including in patients who received Kisunla Dosing Regimen 2 (n=212).

Incidence of ARIA

A lower incidence of ARIA was observed with Dosing Regimen 2 as compared to Dosing Regimen 1. Therefore, Dosing Regimen 2 is the recommended dosage for Kisunla.

In Study 1, symptomatic ARIA-E occurred in 6% of patients through 18 months of treatment with Kisunla.

Clinical symptoms associated with ARIA resolved in approximately 85% of those patients.

Including asymptomatic radiographic events, ARIA, ARIA-E, and ARIA-H were observed with Kisunla: 36%, 24%, and 31% of patients treated with Kisunla, respectively compared to 14%, 2%, and 13% of patients on placebo. There was no increase in isolated ARIA-H for Kisunla vs placebo.

In Study 2, symptomatic ARIA-E occurred in 3% of patients and symptomatic ARIA-H occurred in less than 1% of patients through 12 months of treatment with Kisunla. Clinical symptoms associated with ARIA-E resolved in approximately 67% of patients at 12 months. Including asymptomatic radiographic events, ARIA, ARIA-E, and ARIA-H were observed in 29%, 16%, and 25% of patients treated with Kisunla.

Incidence of Intracerebral Hemorrhage (ICH)

ICH >1 cm in diameter was reported in 0.5% of patients treated with Kisunla vs 0.2% on placebo in Study 1 and in 1% of patients treated with Kisunla in Study 2. Fatal events of ICH have been observed in patients taking Kisunla.

Risk Factors for ARIA and ICH

ApoE ε4 Carrier Status

The risk of ARIA, including symptomatic and serious ARIA, is increased in ApoE ε4 homozygotes.

Recommendations for management of ARIA do not differ based on ApoE ε4 carrier status. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. An FDA-authorized test for detection of ApoE ε4 alleles is not currently available. Currently available tests may vary in accuracy and design.

Radiographic Findings of Cerebral Amyloid Angiopathy (CAA)

Neuroimaging findings that may indicate CAA include evidence of prior ICH, cerebral microhemorrhage, and cortical superficial siderosis. CAA has an increased risk for ICH. The presence of an ApoE ε4 allele is also associated with CAA.

The baseline presence of at least 2 microhemorrhages or the presence of at least 1 area of superficial siderosis on magnetic resonance imaging (MRI), which may be suggestive of CAA, were identified as risk factors for ARIA. Patients were excluded from enrollment in Study 1 and Study 2 for findings on neuroimaging of prior ICH >1 cm in diameter, >4 microhemorrhages, >1 area of superficial siderosis, severe white matter disease, and vasogenic edema.

Concomitant Antithrombotic or Thrombolytic Medication

In Study 1, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed. The majority of exposures to antithrombotic medications were to aspirin. The number of events and the limited exposure to non-aspirin antithrombotic medications limit definitive conclusions about the risk of ARIA or ICH in patients taking antithrombotic medications.

One fatal ICH occurred in a patient taking Kisunla in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent in Study 1, and one fatal intracerebral hemorrhage occurred in the setting of ARIA and the use of a thrombolytic agent in Study 2. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E, and additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (eg, tissue plasminogen activator) to a patient being treated with Kisunla. Advise patients to carry information that they are being treated with Kisunla.

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IMPORTANT SAFETY INFORMATION FOR Kisunla® (donanemab-azbt) (CONT'D)

Amyloid-Related Imaging Abnormalities (ARIA) (Cont'd)

Concomitant Antithrombotic or Thrombolytic Medication (cont'd)

Caution should be exercised when considering the use of Kisunla in patients with factors that indicate an increased risk for ICH and in particular for patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of CAA.

Monitoring and Dose Management Guidelines

Obtain a recent baseline brain MRI prior to initiating treatment and prior to the 2nd, 3rd, 4th, and 7th infusions. Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with Kisunla. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment.

Recommendations for dosing in patients with ARIA-E and ARIA-H depend on clinical symptoms and radiographic severity. Depending on ARIA severity, use clinical judgment in considering whether to continue dosing, interrupt treatment, or permanently discontinue Kisunla. See Prescribing Information for additional dosing considerations.

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have occurred in patients who were treated with Kisunla. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction and initiate appropriate therapy.

Infusion-Related Reactions (IRR)

IRRs were observed with Kisunla with the majority occurring within the first 4 infusions. Most IRRs occurred during the infusion or within 30 minutes after completion of the infusion, however some have occurred hours after an infusion. Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, flushing, difficulty breathing/dyspnea, sweating, elevated blood pressure, headache, chest pain, and low blood pressure.

In the event of an IRR, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Consider pre-treatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing.

Adverse Reactions: The most common adverse reactions reported in ≥5% of patients treated with Kisunla and ≥2% higher than placebo were ARIA-H microhemorrhage, ARIA-E, ARIA-H superficial siderosis, headache, and IRRs.

Kisunla (donanemab-azbt) injection for intravenous use is available as a 350 mg/20 mL single-dose vial.

Please see full Prescribing Information, including Boxed Warning regarding ARIA, and Medication Guide.

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