

An Analysis of Whether Plasma P-tau217 Can Detect Amyloid Clearance Following Donanemab in Early Symptomatic Alzheimer’s Disease

This information is intended for U.S HCPs for medical, scientific and educational purposes. Not intended for product promotion.

The use of plasma P-tau217 to detect treatment-related amyloid clearance following donanemab treatment has not been approved or cleared by the FDA, and the safety and effectiveness of this use have not been established.

Donanemab is an amyloid beta-directed antibody approved for the treatment of Alzheimer’s disease (AD). Treatment with donanemab should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

Despite reductions in plasma P-tau217 with donanemab treatment, this biomarker cannot currently be used to detect TRAC by PET (<24.1 centiloids) in individuals with ESAD. Consider stopping dosing with donanemab based on reduction of amyloid plaques to minimal levels on amyloid PET imaging.



Click **HERE** to see the full results published in **ALZHEIMER’S & DEMENTIA**

The study was supported by Eli Lilly and Company.

All of the authors of the publication were employees of, consultants to, or received compensation from Eli Lilly. Emily C. Collins, Ming Lu, Rose Beck, James Hendrix, Michael E. Hodsdon, Oskar Hansson

Limitations of this analysis of donanemab:

- Only two plasma P-tau217 assays were evaluated, and it is possible that different results would have been obtained with other assays.
- The data analyzed in this study were from a specific clinical trial cohort of individuals with early symptomatic Alzheimer’s disease (ESAD) enrolled in the TRAILBLAZER-ALZ 2 trial, precluding the generalization of the conclusion to more diverse, real-world populations with ESAD.

Highlights of Prescribing Information

These highlights do not include all the information needed to use donanemab safely and effectively. See full [prescribing information](#) for donanemab.

WARNING: AMYLOID RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including donanemab, can cause amyloid related imaging abnormalities (ARIA), as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). ARIA is usually asymptomatic, although serious and life-threatening events can occur. ARIA can be fatal. Serious intracerebral hemorrhages >1 cm have occurred in patients treated with this class of medications. ARIA-E can cause focal neurologic deficits that can mimic ischemic stroke.

ApoE ε4 Homozygotes

Patients treated with this class of medications, including donanemab, who are ApoE ε4 homozygotes have a higher incidence of ARIA, including symptomatic and serious 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 implications of genetic testing results should be discussed with patients.

Consider the benefit for the treatment of Alzheimer’s disease and risk of ARIA when deciding to treat with donanemab.

CONTRAINDICATIONS

Donanemab is contraindicated in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients.

WARNINGS AND PRECAUTIONS

- Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with donanemab. Risk of ARIA, including symptomatic ARIA, was increased in apolipoprotein ε4 (ApoE ε4) homozygotes compared to heterozygotes and noncarriers. The risk of ARIA-E and ARIA-H is increased in donanemab-treated patients with pretreatment microhemorrhages and/or superficial siderosis. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI scanning if indicated.
- Infusion-Related Reactions: 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.