Drug Express

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Weekly New Drug Approvals

Jul. 8th 2024

Donanemab

FDA Approval Date: Jul 2th, 2024

Brand name: Kisunla

Indication: Alzheimer Disease

Mechanism: 3pE-modified Aβ inhibitors

Dosage form: Injection for intravenous use

Company: Eli Lilly

Donanemab, aka N3pG, is a humanized IgG1 monoclonal antibody developed from mouse mE8-IgG2a. This biologic drug recognizes Aβ(p3-42), a pyroglutamate form of Aβ that is aggregated in amyloid plaques.

- In the TRAILBLAZER-ALZ 2 Phase 3 study, people who were the least advanced in the disease experienced the strongest results with Kisunla. Trial participants were analyzed over 18 months in two groupings: one group who was less advanced in their disease (those with low to medium levels of tau protein) and the overall population, which also included participants with high tau levels. Treatment with Kisunla significantly slowed clinical decline in both groups. Those individuals treated with Kisunla who were less advanced in their disease showed a significant slowing of decline of 35% compared with placebo on the integrated Alzheimer's Disease Rating Scale (iADRS), which measures memory, thinking, and daily functioning.

- Kisunla can cause amyloid-related imaging abnormalities (ARIA), which is a potential side effect with amyloid plaque-targeting therapies that does not usually cause symptoms.