Donanemab Receives Full FDA Approval

The US Food and Drug Administration (FDA) approved donanemab (Kisunla) on July 2nd, 2024, for the treatment of early stages of Alzheimer disease. Donanemab is a monoclonal antibody that targets beta-amyloid, one of the abnormal proteins in Alzheimer disease, for removal from the brain. It is administrated intravenously every 4 weeks for 18 months, although it can be discontinued prior to 18 months once amyloid is successfully cleared from the brain. In a recently published clinical trial, donanemab was shown to reduce the progression of cognitive decline and maintain independence in everyday activities. Click to review publication of trial data.

The main side effects of donanemab are swelling and bleeding in the brain discovered on a brain MRI, collectively known as *amyloid related imaging abnormalities (ARIA)*. ARIA occurred in 37% of trial participants receiving donanemab, although most ARIA did not cause symptoms. Symptoms due to ARIA developed in 6% of trial participants treated with donanemab. Serious symptoms of ARIA occurred in 1.6% of people on donanemab. ARIA was more common in people with the e4 variant of the APOE gene.

Donanemab joins lecanemab (Leqembi) as the 2nd FDA-approved anti-amyloid antibody treatment approved for Alzheimer disease in the past year. Although the medications have a similar mechanism of action, there are advantages and disadvantages to each.

The MGB Alzheimer Therapeutic Program (ATP) is enthusiastic about the FDA approval of donanemab and is seeking to add this medication to the MGB hospital formularies as quickly as possible in our preparations to deliver the medication. Like all new medications, donanemab will be carefully reviewed by the MGB Pharmacy and Therapeutics Committee, a process which can take weeks to month. If/when donanemab is approved by this committee, members of the ATP will work with eligible patients to discuss the pros and cons of treatment with lecanamab vs donanemab.

We continue to accept new referrals to determine eligibility for anti-amyloid therapies and to initiate and oversee treatment with them.