BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

US FDA approves Japanese pharma firm Eisai's treatment of Alzheimer's Disease

July 10, 2023 | News

First and only approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline in adults with Alzheimer's disease

Japan-headquartered Eisai Co. and US-based Biogen Inc. have announced that the US Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) supporting the traditional approval of LEQEMBI (lecanemab-irmb) 100 mg/mL injection for intravenous use, making LEQEMBI the first and only approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline in adults with Alzheimer's disease (AD).

LEQEMBI demonstrated clinically meaningful slowing of cognitive and functional decline in a patient group generalisable to US Medicare beneficiaries, which included a mix of racial and ethnic groups, patients with common comorbid conditions, concomitant medications and patients with mild cognitive impairment (MCI) due to AD or mild AD. Treatment with LEQEMBI should be initiated in patients with MCI or mild dementia stage of disease, (collectively referred to as early AD) the population in which treatment was initiated in clinical trials.

LEQEMBI is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid beta (A?).

Eisai serves as the lead of LEQEMBI development and regulatory submissions globally with both Eisai and Biogen co-commercialising and co-promoting the product and Eisai having final decision-making authority.