European Commission Grants Marketing Authorization for Leqembi® (lecanemab)

The European Commission (EC) has granted the amyloid-beta (Aβ) monoclonal antibody Leqembi® (lecanemab) Marketing Authorization (MA) in the European Union (EU). Lecanemab is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment (MCI) and mild dementia due to AD (early AD) who are apolipoprotein E ε4 (ApoE ε4*) non-carriers or heterozygotes with confirmed amyloid pathology.[1]

A link to the press release from the European Commission is available here.

Eisai and Biogen will issue a full press release on the approval this evening.

1. European Medicines Agency Summary of Product Characteristics (SmPC)