Leqembi™ (lecanemab-irmb) – FDA accepts application for traditional approval

- On March 6, 2023, Eisai and Biogen announced that the FDA has accepted their supplemental Biologics License Application (sBLA) for Leqembi (lecanemab-irmb), requesting the conversion of the accelerated approval of Leqembi to a traditional (full) approval.

- The Leqembi application has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of July 6, 2023.

- The FDA is currently planning to hold an Advisory Committee to discuss this application but has not yet publicly announced the date of the meeting.

- Leqembi is a beta amyloid targeted therapy currently approved under the Accelerated Approval Pathway for the treatment of Alzheimer's disease.

    — Leqembi was approved under accelerated approval based on Phase 2 data that demonstrated that Leqembi reduced the accumulation of amyloid beta plaques in the brain.
    — Continued approval was contingent upon verification of Leqembi's clinical benefit in a confirmatory trial.

- The sBLA for converting the accelerated approval to a traditional approval is based on the findings from the Phase 3, Clarity AD trial. In that study, Leqembi met the primary endpoint by reducing clinical decline on the Clinical Dementia Rating–Sum of Boxes (CDR-SB) score by 27% compared with placebo, which represented a treatment difference -0.45 ($p < 0.001$).

    — The FDA has determined that the results of Clarity AD can serve as the confirmatory study to verify the clinical benefit of Leqembi.

- Due to a CMS national coverage determination (NCD) for beta amyloid targeted therapies, coverage for Leqembi is restricted to patients enrolled in a randomized clinical trial due to its accelerated approval status.

    — On February 22, CMS reaffirmed that under the NCD, if a beta amyloid targeted therapy receives traditional FDA approval, CMS will provide broader coverage on the same day. As noted in the NCD, coverage would be expanded to include registry-based studies that reflect real-world care.