Leqembi™ (lecanemab-irmb) – FDA Advisory Committee update

- On June 9, 2023, the FDA convened a Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) meeting to discuss Eisai/Biogen's Leqembi (lecanemab) for the treatment of early Alzheimer's disease.

- The FDA Advisory Committee reviewed Eisai's supplemental Biologics License Application (sBLA) to convert the accelerated approval to a traditional (full) approval.

- Leqembi, an amyloid beta-directed antibody, is currently approved via accelerated approval for treatment of Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease.

- 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 = 0.00005).

    — The identified risks with Leqembi use included amyloid-related imaging abnormalities (ARIA) and infusion-related reactions, which are currently described in the *Warnings* section of the Leqembi drug label.

- Panelists on the Advisory Committee **voted unanimously (6 to 0) in favor of clinical benefit** being demonstrated by the CLARITY AD trial.

- The FDA is expected to make an approval decision for the traditional approval by July 6, 2023.

- Based on a CMS national coverage determination (NCD), current Medicare coverage for any beta-amyloid targeted therapy approved via the accelerated approval pathway is restricted to patients enrolled in a randomized clinical trial.

- On June 1, 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.

    — Clinicians will be able to submit evidence through a nationwide, CMS-facilitated portal. CMS is working with multiple organizations that are getting ready to open their own registries.
    — No other details are known about the CMS registry, or the data that will be required.