July 5, 2023

Leqembi FDA Approval: Slow Uptake To Follow

Clinical Protocols & CMS Coverage with New Registry

Relevant Companies

Our Take & Next Up

Assuming traditional FDA approval by the end of the week Leqembi (Eisai/Biogen) uptake will be slow as neurology clinics and academic medical centers establish internal patient selection & treatment protocols, while learning to manage a new national registry required for Medicare coverage. While the FDA is not required to follow committee recommendations, we expect Leqembi to receive full approval by its PDUFA date of July 6.

Leqembi treatments are expected to start within weeks in patients with MCI and mild AD and will be administered every two weeks via intravenous infusion ($26,500 annual cost). Neurologists will administer treatment and eventually clinics, geriatric and family health centers, as well as traditional physician offices will have the ability to provide Leqembi with necessary clinical follow-up.

Due to Leqembi's CMS registry requirements for all mAbs, along with launch dynamics, patient selection & follow-up, it will take weeks-then-months before the drug becomes more widely disseminated. We explore the next steps for Alzheimer's approvals, including the tau hypothesis, below.

Key Points

FDA

On June 9, FDA's Peripheral and Central Drugs Advisory Committee voted 6-0 that a Phase 3 study of Leqembi confirmed its clinical benefit for those with early-stage Alzheimer's disease and recommended full FDA approval of the drug. Link to

meeting details here. We expect full FDA approval to occur by July 6th, the given PDUFA date, and CMS coverage to be available upon traditional approval ...

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