ENDPOINTS NEWS

CMS as gatekeeper: Why lecanemab is similar but also very different from Aduhelm

by **Zachary Brennan** on September 28th, 2022

Both aducanumab and lecanemab — Eisai and Biogen's Alzheimer's drugs — are not only targeted at reducing the clumped beta-amyloid that has mystified and encouraged researchers for decades, using the same FDA accelerated approval pathway, and could also put a serious dent in Medicare's budget.

Last night's big unveiling of encouraging data for lecanemab — as clear a win as any in Alzheimer's — also brought back memories of Aduhelm's quick accelerated approval and tepid launch, thanks in a large part to CMS' ultimate decision to require additional RCT data for the entire class of anti-amyloid mAbs.

But in the case of lecanemab, yesterday's announcement regarding its ability to slow the rate of cognitive decline by 27% over 18 months versus placebo should be good enough to not only convert an accelerated approval to a full one in the FDA's eyes, but to confirm exactly what CMS means when it asks, "Does the anti-amyloid mAb meaningfully improve health outcomes (i.e., slow the decline of cognition and function) for patients in broad community practice?"

Whereas Aduhelm was studied in almost an exclusively white population, Eisai recruited about 25% of its total US enrollment from Hispanic and Black communities, which meets the diversity criteria specified by CMS, according to SVB Leerink.

While Eisai says it's still working with CMS, and the FDA has until Jan. 6 to make an official decision on accelerated approval, the data still need to be presented next month at the CTAD conference in San Francisco, and published, with more discussion likely focusing on the clinical benefit, and the safety profile of lecanemab as the companies said total incidence of amyloid-related imaging abnormalities were in line with past data (ARIA-E and/or ARIA-H) or 21% in the lecanemab group vs. 9% in the placebo group.

The bigger question may be what this level of slowing the rate of cognitive decline is worth — in patient and value terms.

Eisai said in June that its annual value-based price of lecanemab "was estimated at $9,249 to $35,605 (Societal perspective: $10,400 to $38,053)" based on an early economic assessment.

And surely Eisai learned its lesson from Biogen's fiasco with Aduhelm's price slashed in half to $28,200 less than six months after launch. And where many thought Aduhelm could be the straw that breaks Medicare's back, with tens of billions in new sales following approval, lecanemab could create the same sort of issues for government spending.

Ironically, President Joe Biden and his administration just yesterday announced and celebrated the fact that Medicare premiums next year would actually decline, thanks in a large part to Aduhelm's lackluster traction and as CMS had previously projected billions of sales. Perhaps CMS will need to readjust those premium levels again given last night's data.

Regardless, an FDA adcomm meeting to discuss the lecanemab data seems likely given the high stakes nature of the announcement made last night and the stock market reaction — Biogen shares $BIIB were up almost 50% in pre-market trading this morning, and even Roche $RHHBY, with another potential anti-amyloid drug on the way, was up 7%, as was Eli Lilly $LLY up almost 8%.

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