Alzheimer's drug Leqembi

Expected to be Approved by the US FDA

Leqembi (Lecanemab), a new drug for Alzheimer's disease jointly developed by Eisai of Japan and Biogen of the United States, will become the first new drug for Alzheimer's disease to be fully approved by the FDA in 20 years.

On June 9, local time, the US Food and Drug Administration (FDA) Peripheral and Central Nervous System Drugs Advisory Committee (hereinafter referred to as the "FDA Advisory Committee") fully approve Leqembi. The FDA's final decision is expected on or before July 6.
In January 2023, Leqembi received accelerated approval from the US FDA for marketing, priced at US$26,500/year. Full approval also means that treatment with the drug can be covered by Medicare in patients with mild cognitive impairment or the mild dementia stage of the disease with proven amyloid-beta pathology.

Previously, Aduhelm, another Alzheimer's disease drug that was launched earlier by the above two companies, was limited to medical insurance coverage due to efficacy issues, and was strictly limited to only patients participating in clinical trials. In April 2022, the decision made by the US Centers for Medicare and Medicaid Services (CMS) has largely affected the prescription and use of Aduhelm in routine clinical practice. Leqembi, which received accelerated approval, is currently subject to the same restrictions.

In a pivotal placebo-controlled trial called CLARITY AD, Leqembi demonstrated positive efficacy. After 18 months of treatment with Leqembi, patients experienced a 27% slower rate of cognitive and functional decline compared with placebo. According to industry media Endpoints, Dr. Sharon Cohen, medical director of the Toronto Memory Program (TMP), was one of the participants in the study and spoke on behalf of Eisai at the conference. Both the literature and Alzheimer's disease experts agree that a 20% to 30% reduction in disease is clinically meaningful, she said.

The expert consultants who participated in the voting all affirmed the positive clinical benefits of Leqembi. Merit Cudkowicz, from Harvard Medical School, said the evidence for Leqembi's clinical benefit was clear, and she was impressed with the drug's efficacy seen early on and increased over time," For diseases that don't have many treatment options, these changes are meaningful."

"It's an absolutely small addition to the question that everyone is grappling with as to what the clinical significance is," said another committee member, Tanya Simuni, a professor of neurology at Northwestern University Feinberg School of Medicine.

Kudkovic also asked the FDA what data could be collected to inform uncertainty about Leqembi use. In this regard, Teresa Buracchio (TB), acting director of the US FDA Office of Neuroscience, pointed out that according to certain safety monitoring measures under the accelerated approval of Leqembi, Eisai needs to submit a rapid report and collect more adverse event data. FDA may update drug labeling as more registrations are made.

Ahead of this discussion, an FDA advisory committee issued a briefing document suggesting support for full approval. The filing cites Leqembi's demonstration of a treatment effect in a pivotal clinical confirmatory trial called "Study 301", supported by consistent favorable results across primary and secondary endpoints in prespecified subgroups of interest.

In terms of safety, the document noted risks of amyloid-related imaging abnormalities, intracerebral hemorrhage, and infusion-related reactions, but the reviewers argued that "risks can be described in the prescribing information and do not appear to preclude full approval of Leqembi." .

Before the meeting, committee member David Weisman, MD, withdrew due to a conflict of interest. He signed an open letter from the Alzheimer's Association supporting full approval of Leqembi and asking CMS to revisit Medicare coverage policies, which will also be submitted for review at the meeting.

However, some U.S. Democratic lawmakers are in the opposition camp. On June 7, local time, the head of the U.S. Senate Health Committee, Senator Bernie Sanders, sent a letter to the U.S. Secretary of Health, asking him to "full use" of his powers to ensure that Medicare does not pay Leqembi's high ratings price.

He believes that the price of 26,500 US dollars per year is unreasonable, and suggests that the

Biden administration should break patents or create a demonstration project that pays for medicines at a lower price, "Alzheimer's disease is a terrible disease. We must do our best. All that is possible to find a cure for millions of patients. But we cannot allow the pharmaceutical companies to bankrupt Medicare and the federal government in the process".