US FDA clears first blood test for Alzheimer's detection

Sign is seen outside of the Food and Drug Administration (FDA) headquarters in White Oak, Maryland, U.S., August 29, 2020.

May 16 (Reuters) - The U.S. Food and Drug Administration has cleared Fujirebio Diagnostics' blood test to diagnose Alzheimer's disease, the regulator said on Friday, making the device the first of its kind to detect the brain-wasting condition.

Blood tests could speed up diagnosis of the disease and make it easier for more people to access its treatments such as Biogen (BIIB.O), opens new tab and Eisai's (4523.T), opens new tab Leqembi and Eli Lilly's (LLY.N), opens new tab Kisunla, since traditional tests are often costly or uncomfortable.

Fujirebio's test, branded as Lumipulse, checks for two proteins in the blood and uses their ratio to help detect signs of amyloid beta plaque, considered a hallmark of the disease, in the brain.

Other options to detect Alzheimer's include procedures such as a spinal tap, which requires an invasive puncture to collect spinal fluid, or an expensive PET brain scan that may not be reimbursed by health insurers.

"Street expectations for both therapies (Leqembi and Kisunla) are modest" with a slow ramp over the next few years, given the lack of access to neurologists, said Citi analyst Geoffrey Meacham. "An approved blood-based diagnostic is a positive in a disease area that has been starved of game-changing innovation."

Biogen has been doubling down on Leqembi but it has failed to live up to lofty expectations due to concerns over cost, efficacy and side effects.

In the first quarter, Leqembi brought $96 million in sales, while Lilly recorded $21.5 million in Kisunla sales.

Lumipulse and C2N Diagnostics' PrecivityAD2 were the top two performers when compared with four other commercial blood tests for Alzheimer's, according to a study, opens new tab led by researchers at Washington University School of Medicine.

Biogen has partnered, opens new tab with Fujirebio, and Eisai is collaborating, opens new tab with C2N to clinically advance and commercialize blood tests that can detect Alzheimer's risk.

News Source:

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