Q&A: Experts discuss pros, cons of new Alzheimer's drug

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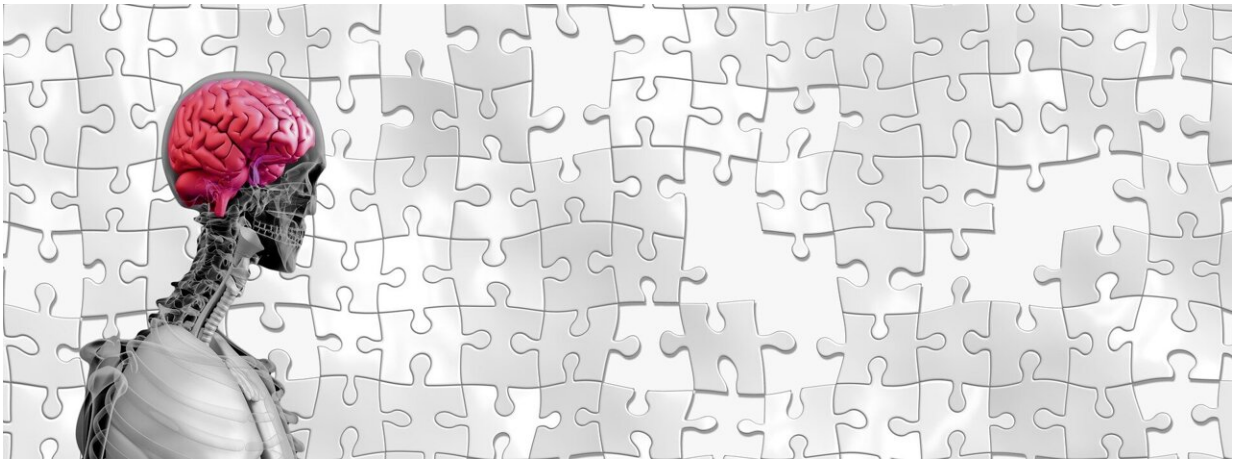

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Patient care teams are preparing to offer lecanemab, a new Alzheimer's disease treatment expected to soon receive approval from the U.S. Food and Drug Administration (FDA), to patients in the coming months.

"This is the most promising therapy yet for Alzheimer's disease, but delivering the treatment to patients is far from simple," said Sarah Kremen, MD, who leads the Alzheimer's Disease Clinical Trial Program in the Department of Neurology at Cedars-Sinai. "We want to be sure that potential patients understand the treatment process and risks, and are clear about what type of real-world gains it might deliver."

Lecanemab, marketed under the brand name Leqembi, isn't a perfect solution, but it is a positive step forward, said Zaldy Tan, MD, MPH, medical director of the Jona Goldrich Center for Alzheimer's and Memory Disorders in the Department of Neurology at Cedars-Sinai.

"More than 6 million people in the U.S. are diagnosed with Alzheimer's disease, and this is the most effective treatment we have available," Tan said. "We have to start somewhere."

Kremen and Tan sat down with the Cedars-Sinai Newsroom to explain the screening and treatment process for patients interested in receiving lecanemab, and its risks and benefits.

How does lecanemab work-and how well?

Kremen: Clinical trial data showed that the treatment can pull amyloid-a protein that forms plaques and disrupts brain function-out of the brain in a significant way. Patients receiving lecanemab during clinical trials also showed moderately less decline on tests of memory and functional ability.

Lecanemab also seems to decrease accumulation of tau protein, which forms tangles inside neurons of Alzheimer's patients, particularly in the memory centers of the brain. That being said, treatment takes 18 months and only slows cognitive decline by about six months.

When will Cedars-Sinai start administering lecanemab to patients?

Tan: Cedars-Sinai hopes to begin offering this treatment in the next few months. Our multidisciplinary team-including experts in cognitive testing, brain imaging, pharmacy, infusion therapy and patient care

coordination-has been working to create a robust process that will support patients from pre-treatment screening through follow-up care and account for every anticipated challenge that might present itself.

Who can be treated with lecanemab?

Kremen: This treatment is designed for people who have either mild cognitive impairment or mild dementia due to Alzheimer's disease. This is not for people with moderate or severe dementia, where their memory and other cognitive functions are so impacted that they need to rely on other people for help with daily living.

It is also not for people at risk for Alzheimer's disease but who have normal memory and thinking. The medication isn't recommended for anyone taking blood thinners or who has significant brain bleeds, brain swelling, aneurysms, vascular malformation, brain tumors, or an uncontrolled bleeding disorder.

What kind of real-world benefits might the drug have for patients?

Tan: We don't yet know how many people will have observable benefits from this medication. We're hopeful that it's going to prolong our patients' ability to function, but that might be a difference of as little as three months' delay in disease progression. Still, three more months of better thinking and participating in activities of daily life may be meaningful to some of our patients and their families as they navigate this condition.

What are the risks associated with treatment?

Kremen: Risks include brain bleeding and brain swelling, which is also

true of other, similar Alzheimer's disease treatments that haven't made it this far in clinical research tests. The side effect we're most concerned about is large brain bleeds, which are fairly rare but can happen. So people need to go into this with eyes open, because we're not going to be able to completely mitigate this risk.

What is the treatment process like?

Tan: The medication is given by IV infusion over one hour, every two weeks-so the time commitment is something to consider. And patients will need to have an MRI before the fifth, seventh and 14th infusions, according to FDA guidelines, so that we can monitor for brain swelling and brain bleeds. We will also have to monitor for infusion reactions, such as low blood pressure or difficulty breathing, which could happen during any type of IV infusion. We will monitor for three hours after the patient's first dose, two hours after the second and third doses, and 30 minutes after the remaining doses for patients who do not have infusion-related reactions.

What types of pre-treatment testing will patients need?

Kremen: Patients will need a diagnostic evaluation to confirm that their dementia or cognitive impairment is due to Alzheimer's disease and not something else. This evaluation can be done by a primary care doctor, geriatrician, neurologist or psychiatrist. They will also need testing to confirm the presence of amyloid, which is what the medication is designed to treat.

This can be done via specialized brain imaging-which is not widely available or covered by insurance-or through spinal fluid tests. Patients will also need genetic testing, because those with one or two copies of a

gene called APOE4 are at increased risk of brain bleeds and swelling and will need to take this into account when deciding whether to be treated.

What costs are associated with treatment?

Tan: According to lecanemab's manufacturer, Eisai, the drug itself will cost around $26,500 per year, and there are additional costs for required pre-treatment testing and monitoring during treatment. The Centers for Medicare & Medicaid Services has stated that if lecanemab receives full FDA approval, Medicare will cover the treatment in "appropriate settings." It is still unclear whether Medicare or private insurers will cover testing and monitoring, and the out-of-pocket cost to patients is uncertain.

Provided by Cedars-Sinai Medical Center

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