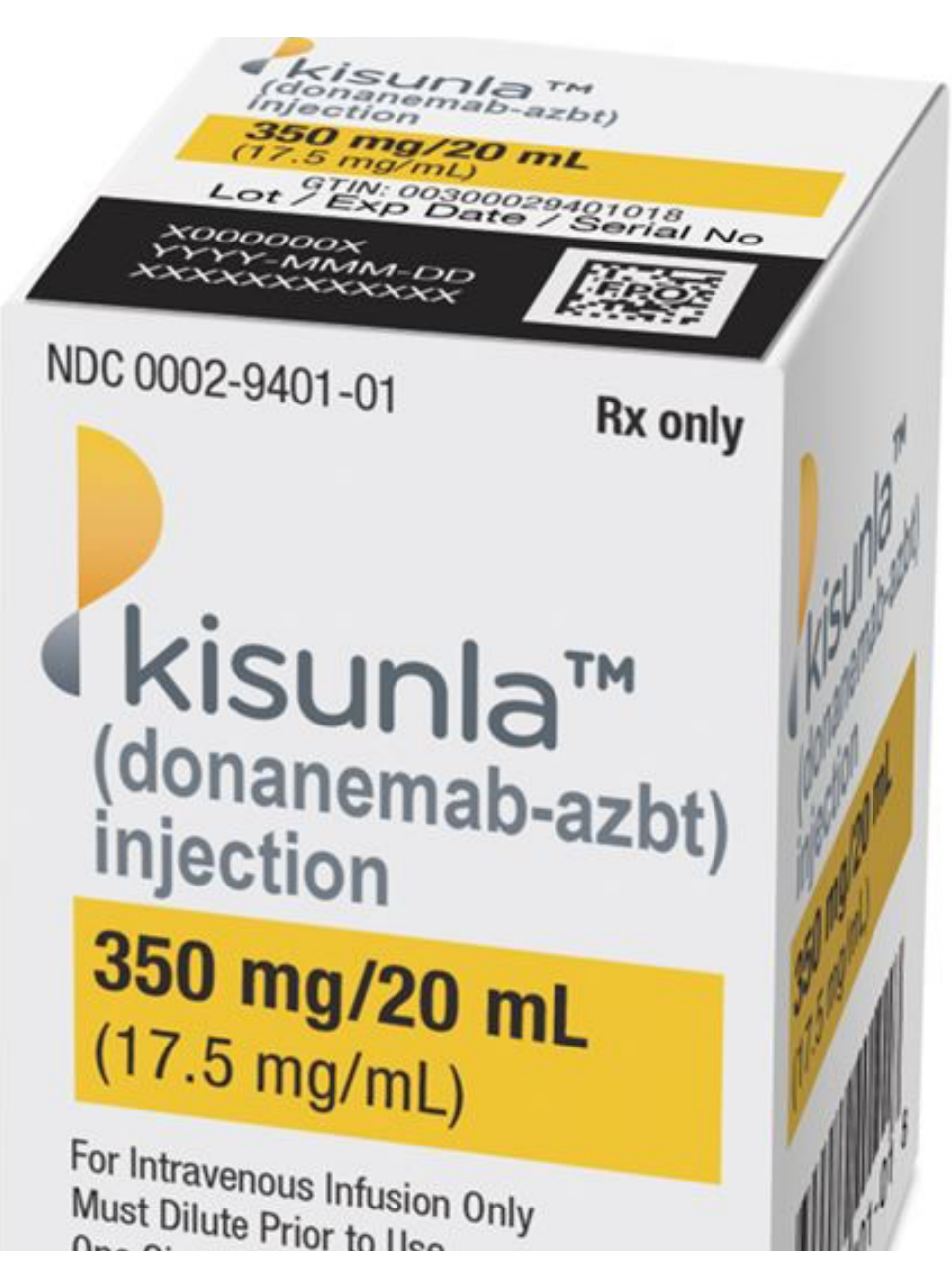

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'The good thing is, now there are choices': Federal approval of new Alzheimer's drug offers a welcome option

The drug, a series of infusions across 18 months, does boast a hefty price tag

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A new drug for the treatment of Alzheimer's disease was approved by the Food and Drug Administration on Tuesday, providing an option for some where the choices remain few.

Eli Lilly's Kisunla is for the treatment of mild cognitive impairment in adults with Alzheimer's disease. A similar Alzheimer's dementia drug — Leqembi from Japan's Eisai, which is also administered by infusion — was approved by the FDA last year.

"The good thing is, now there are choices," said Marc Haut, director of the Memory Health Clinic at West Virginia University's Rockefeller Neuroscience Institute. "We wish [the drug] worked a little better, but this is a great first step."

More than 282,000 Pennsylvanians are living with Alzheimer's, representing over 11% of the population older than 65 years of age. There is currently no cure for this disease, which leads to progressive cognitive and memory decline over time.

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Allegheny County is also home to a larger percentage of older adults, at 27%, compared to the national average of 23%, per Allegheny County's Area Agency on Aging Annual Report, and has more than 200 senior living and dementia facilities.

The Kisunla (generic name, donanemab-azbt) clinical study was funded by Indianapolis-based Eli Lilly. A Phase 3 clinical trial with 1,736 participants across multiple institutions, the study found that the drug slowed cognitive decline and reduced build-up of amyloid plaque — suspected to be a key reason for nerve and cell damage in the brain.

"This is real progress," said Alzheimer's Association president and CEO Joanne Pike in a July 2 statement regarding the drug's approval. "Today's approval allows people more options and greater opportunity to have more time."

Eli Lilly said Medicare and financial support is possible for those who qualify.

"We know these medicines have the greatest potential benefit when people are treated earlier in their disease, and we are working hard in partnership with others to improve detection and diagnosis," said Anne White, executive vice president of Eli Lilly and Company and president of Lilly Neuroscience, in a Tuesday news release about Kisunla's approval. "Each year, more and more people are at risk for this disease, and we are determined to make life better for them."

While experts lauded the federal approval, some noted key factors of the study to heed. For one, just 2% of the study participants were Black, whereas Alzheimer's and related dementia disproportionately affects the Black population, which is two times more likely than whites to develop the disease. The Black population may also suffer from a lack of access to services due to the high cost of caregivers and insurance to cover medications.

"The Alzheimer's Association is disappointed that so little progress is being made to improve representation of all affected populations in Alzheimer's clinical trials," the organization said in Tuesday's statement. "It is critical that clinical trial study populations reflect the communities these treatments intend to serve."

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Dr. Haut called the approval "really good news," and noted that it gives patients options for a condition that currently has very few.

WVU has already submitted a request that the drug be evaluated for the health system to administer, he said, which may take 30 to 60 days.

The drug boasts a hefty price tag of $48,000 for 18 months of treatment, though Eli Lilly said in the release that Medicare coverage is available for those eligible.

"This could be a lot of money for some people who are on a fixed income," said Dr. Haut.

But many patients with Medicare have secondary insurances to help cover costs, he said, and traditional FDA approval, as well as the fact that the drug is stopped after a certain number of infusions, may encourage the Center for Medicare and Medicaid Services to cover costs.

A type of brain bleeding called Amyloid-Related Imaging Abnormalities (ARIA) has been a concern during the length of the clinical trials. Per the study results, 37% of those who received the drug developed ARIA, compared to 15% in the placebo group.

While a majority of those who developed ARIA resolved the condition without conflict, three patient deaths were thought to have been directly related to the Kisunla treatment. (Twenty-six patients died over the length of the study in both groups.) Many patients also had infusion-related reactions.

"The side effects are something of an issue," said Stephen Samples, the system chair of neurology for Allegheny Health Network and a physician. "But while there are risks, there's very little else that's available to people."

Dr. Samples said his father died of Alzheimer's and that this approval gives hope and promise to thousands of families that are suffering from a "devastating" situation.

He also noted that many other drugs have side effects — such as natalizumab, which treats multiple sclerosis — and may lead to an often fatal condition that damages the nerves in the brain.

"People go through a great deal of chemotherapy just to gain a year or so with their families," he said. "The improvement [on Kisunla] is significant, and seems more positive than most."

Barbara Eades, of Chattanooga, Tenn., was diagnosed with mild cognitive impairment in 2018 and participated in the clinical trial.

"I was fortunate to participate … and receive this treatment," she said in the July 2 Alzheimer's Association statement. "It has provided me an opportunity to live my life fully, for more time."

Many of the study authors were employees of Eli Lilly and were personal share- and stockholders of the company, which they disclosed in the journal article, published in JAMA. Dr. Haut sees this as a conflict of interest, but isn't sure how much of an impact it will have on the benefit of the medicine itself.

"Our job is to dig in and look at all the data really carefully, and see what we think about it," he said. "If we think it's safe, we'll start using it, and go from there. At first glance, the data looks reasonable. We'll figure things out as we go."

Dr. Samples said he was "cautiously excited" and optimistic about the news, and that he is already receiving emails regarding the medication.

How quickly it will be rolled out is not yet clear, but the process could take months.

"There are a lot more people who want [Kisunla] than can qualify," said Dr. Haut. "Hopefully going forward, there will be new pathways for patients who don't qualify for these infusions."

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