

## Neurologist Dr. Mateja de Leonni Stanonik provides update on two infusion medications for Alzheimer's disease

Today, Alzheimer's disease is the most common cause of dementia, responsible for more than 60% of all such cases, affecting more than 6 million Americans.

TUCSON, ARIZONA, USA, June 10, 2023 /EINPresswire.com/ -- Not all of us are so fortunate to age gracefully, one of the reasons being Alzheimer's disease ("Alzheimer's"). This disease causes memory loss and cognitive disabilities that can seriously affect daily life. You may have a loved one, or know someone, who is afflicted with this disease, becoming gradually more and



Dr. Mateja de Leonni Stanonik, Vita Medica Institute, Tucson, Arizona

more incapacitated, and eventually unable to carry out even simple tasks.

Wikipedia describes Alzheimer's as a "neurodegenerative disease that usually starts slowly and



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Dr. Mateja de Leonni Stanonik, Neurologist progressively worsens...The most common early symptom is difficulty in remembering recent events. As the disease advances, symptoms can include problems with language, disorientation (including easily getting lost), mood swings, loss of motivation, self-neglect, and behavioral issues. As a person's condition declines, they often withdraw from family and society. Gradually, bodily functions are lost, ultimately leading to death...Although the speed of progression can vary, the typical life expectancy following diagnosis is three to nine years."

https://en.wikipedia.org/wiki/Alzheimer%27s\_disease

The exact cause of Alzheimer's is elusive. According to

current scientific opinion, it is caused by an abnormal build-up of proteins in and around brain

cells. These proteins are amyloid (which forms plaques around brain cells), and tau (which form tangles within brain cells). The result is a loss of neurons and their connections.

But we don't really know what sets these proteins amyloid and tau in motion. Some genetic and environmental risk factors have been identified. Other risk factors are head injuries, depression, and high blood pressure.

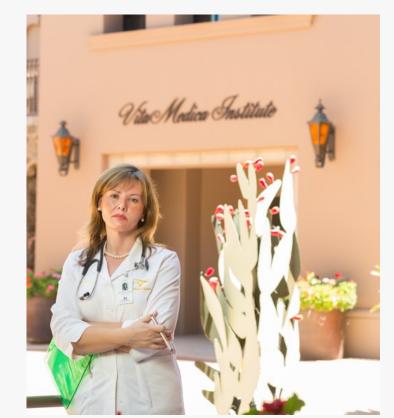
There are several treatment options available for Alzheimer's. Now there are two new treatments, both administered by intravenous infusion, that have shown encouraging results. They are aducanumab and lecanemab.

Aducanumab (marketed as Aduhelm™)

The Food and Drug Administration (abbreviated FDA) approved aducanumab through accelerated approval in June 2021. See <a href="https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug">https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug</a>



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This expedited procedure is sometimes used for treatments for a serious or life-threatening illness that provides a meaningful advantage over existing treatments.

This FDA approval is noteworthy—it was the first in over 18 years. It is the first treatment to attack what many believe is an underlying cause of Alzheimer's disease, the build-up of proteins in the brain. Aducanumab is a so-called monoclonal antibody (MAB) that stimulates the human immune system to break down the plaques that form in the brains of people with dementia.

Based on the recent updated FDA-approved labeling for the treatment, it should be given to

patients with mild cognitive impairment or mild dementia. In clinical trials, the treatment was tested only in patients with early-stage Alzheimer's disease or mild cognitive impairment. It has not been tested on persons with later stages of the disease.

Also, in those clinical tries, the participants underwent PET scans to confirm the protein plaques in their brains. That testing will also apply to patients who receive such treatment, a PET scan or comparable type of imaging.

As with many treatments, it is not without side effects. As for aducanumab, the noted side effects are painful brain swelling (which occurred in about 35% of participants in the clinical trials), and more than 20% of the participants experienced headaches. So brain swelling is something that should be monitored in patients receiving this treatment. Finally, some participants experienced confusion, vision changes, diarrhea, as well as allergic reactions.

The FDA provides more information about the drug on its website: <a href="https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/aducanumab-marketed-aduhelm-information">https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/aducanumab-marketed-aduhelm-information</a>

But note that the treatment is not a cure for Alzheimer's. The treatment cannot reverse the disease progression when symptoms have already set in. It has been reported that some providers, such as The Cleveland Clinic and the U.S. Department of Veterans Affairs, are currently not offering aducanumab.

Lecanemab (marketed as Leqembi™)

Earlier this year, in January, the FDA approved lecanemab as another treatment for early Alzheimer's, also through the accelerated approval procedure because clinical trials have shown that it removes the sticky proteins in the brains of early stage Alzheimer's patients. Thus, it is "reasonably likely" that the



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treatment is effective.

The National Institutes of Health (abbreviated NIH) recently published a related study of lecanemab. See <a href="https://pubmed.ncbi.nlm.nih.gov/36449413/">https://pubmed.ncbi.nlm.nih.gov/36449413/</a>

In brief, the clinical trial had 1,795 participants with early-stage Alzheimer's. The results showed a 27% reduced clinical decline on the global cognitive and functional scale (abbreviated CDR-SB), compared with placebo treatment.

The study concluded that lecanemab resulted in moderately less decline of cognition and function after 18 months. However, it also noted side effects. According to the FDA, the treatment will carry a warning about amyloid related imaging abnormalities (abbreviated ARIA) and infusion related reactions including flu-like symptoms, nausea, vomiting, and changes in blood pressure.

Lecanemab is currently under review with the European Medicines Agency (abbreviated EMA), and approval is expected in the near future. See news report at <a href="https://www.fiercepharma.com/pharma/fda-doc-outlines-apparent-agency-support-full-approval-biogen-eisais-leqembi">https://www.fiercepharma.com/pharma/fda-doc-outlines-apparent-agency-support-full-approval-biogen-eisais-leqembi</a>.

## About Dr. Mateja de Leonni Stanonik

Mateja de Leonni Stanonik, MD, MA, PhD (former Surgeon General of the Republic of Slovenia) is the head of a multidisciplinary <u>Neurology</u> and Psychiatry Clinic, the <u>Vita Medica</u> Institute, in Tucson, Arizona. The focus of her current practice is stroke/vascular neurology, memory issues as well as women's issues within neurological disorders.

Mateja de Leonni Stanonik, BA, BSc, MA, MD, PhD, grew up in Slovenia (formerly Yugoslavia). She completed her undergraduate degrees in Biology and Psychology (BSc.), as well as in German and Political Science (B.A.). She went on to obtain her Master's degree in Cognitive Psychology/Neurolinguistics and Doctoral (Ph.D.) degree in Neuroscience. In 2007, she completed her M.D. degree at the Saba University School of Medicine, followed by a medical residency in Neurology at George Washington University.

Dr. de Leonni Stanonik is passionate about preserving brain health well into the golden years of life which allows patients to maintain quality of life as much as possible. Thus, she routinely uses treatments to limit cognitive decline.

Dr. de Leonni Stanonik at the Vita Medica Institute is the only neurologist in the state of Arizona who regularly prescribes and administers both medications to both domestic and international patients, both as a part of ongoing clinical trials and as regularly prescribed medications to treat early Alzheimer's disease and Mild Cognitive Impairment.

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