# Lecanemab is Neither Safe nor Effective in Treating Alzheimer's Patients ( Alzheimer International Society's  panel)

*Lecanemab is Neither Safe nor Effective in Treating Alzheimer's Patients (according to the Alzheimer International Society's scientific panel)*

Alzheimer International Society

SUNNYVALE, CA, USA, June 28, 2023 /EINPresswire.com/ -- Alzheimer International Society's (AIS) announced today it paneled a group of international experts to discuss the FDA's upcoming decision to fully approve Leqembi (lecanemab). The webinar was held on June 22, 2023 with over 250 attendees from around the world. The panel concluded that lecanemab is neither safe nor effective in treating patients suffering Alzheimer's disease.

> Lecanamab is neither safe nor effective in treating Alzheimer's patients. Numerous trials demonstrate that amyloid removal is without cognitive benefit while risking fatal cerebral bleeding"
>
> *George Perry, PhD,  Editor-in-Chief- Journal of Alzheimer's Disease*

The webinar was opened by Mr. Les Hamasaki, the Executive Director of the Alzheimer International Society. The scientific panelists included:

George Perry, PhD, Editor-in-Chief, Journal of Alzheimer's Disease, Professor & Semmes Distinguished University Chair in Neurobiology, University of Texas at San Antonio.

Diana Zuckerman, PhD, President, National Center for Health Research.

Poul Høilund-Carlsen, MD, MDSc, Professor, Research Unit of Clinical Physiology and Nuclear Medicine, University of Southern Denmark.

Rudolph J. Castellani, MD, Professor, Mesulam Center for Cognitive Neurology and Alzheimer's Disease, Northwestern University.

Zung Vu Tran, PhD, Retired Research Professor, Department of Biostatistics & Informatics, University of Colorado; VP of Bioinformatics for Biomed Industries, Inc. and a scientific advisor for AIS. (moderator)

The panel noted that the Clinical Dementia Rating - Sum of Boxes (CDR-SB) scores increased from a baseline of 3.2 to 4.41 in the lecanemab group, a change of 1.21; and increased from 3.2 to 4.86 in the placebo group, a change of 1.65. The -0.45 difference (4.41-4.86) in the scale of 0-18, between the groups is often represented as 27% less cognitive decline (0.45/1.65). [1] The panelists unanimously agreed that it was a misleading conclusion based on the use of the wrong de-nominator. The correct CDR-SB calculation would give lecanemab a clinical benefit of 9.3% (0.45/4.86), and not 27%. [2]

Dr. Zung Tran stated: “At the end of the 18-month phase 3 trial, the actual CDR-SB scores give lecanemab 9.3% not 27% less cognitive decline as compared to placebo. This was not an improvement, but a less-worse outcome, and it was consistent with the result of 8.7% less cognitive decline in the phase 2b trials of lecanemab. This smaller value is unlikely to make any difference for people living with early AD”.

Dr. Zuckerman said that “the FDA standard for full approval includes evidence that benefits likely outweigh the risks, and benefits should be clinically meaningful. However, the differences are small and the FDA did not point out the MCI fluctuates due to social interactions, depression or other factors.”

The panel discussed the safety issues of lecanemab in Eisai’s Study 301 Core program and open label extension in which the incidence of death was 6.9/1000 person years or 16 deaths among 2,331 participants in the clinical trials of lecanemab. At least two study participants died due to cerebral hemorrhage. [3,4,5]

Prof. Rudolph J. Castellani said “Given the evolving asymmetry between toxicity and benefit, widespread distribution of lecanemab might need to be reconsidered. Unless and until the neurovascular pathology is better accounted for, we need to sort out of those with severe cerebral amyloid angiopathy, a percentage of whom may not survive the therapy, from those without.”

Prof. Poul F. Høilund-Carlsen stated: “The removal of amyloid as assessed by amyloid PET is questionable. In addition, the increased incidence of ARIAs and accelerated loss of brain volume (assessed by MRI) in the lecanemab-treated patients suggests that lecanemab causes increased brain damage.”

Prof. George Perry stated: “Lecanamab is neither safe or effective in treating precious family members suffering Alzheimer's disease. Numerous trials demonstrate the only widespread claim, amyloid removal, is without cognitive benefit while risking fatal cerebral bleeding.”

You can view the webinar at: https://youtu.be/mtvXA6GdGjs

About Alzheimer International Society

Alzheimer International Society™ is a non-profit organization with the goal to facilitate and accelerate research to find prevention and treatment therapeutics for Alzheimer's disease. https://www.alzint.com

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