



SPRING ISSUE 2019

Alzheimer's Association 2019 Facts & Figures

- Between 2000 and 2017, deaths from AD increased 145% while deaths from heart disease decreased 9%
- AD is 6th leading cause of death in the US.
- Alzheimer's Disease kills more seniors than breast cancer and prostate cancer combined.
- **Only 16% (1 in 7) of seniors receive regular cognitive assessments during routine health check-ups.**
- One in 10 age 65 and older has Alzheimer's Dementia
- Almost 2/3 of American with Alzheimer's are women
- Older African Americans are about twice as likely to have AD or other dementias as white.
- Hispanics are about one and on half times as likely to have AD or other dementias as older whites.

Recent Alzheimer's Study Closures

In 2019 two anti-amyloid compounds failed to produce data suggesting the trials would not meet their endpoints in a scheduled interim analysis. One was Genentech's crenezumab in the Phase III CREAD 1 & 2 trials. In the interim analysis, it appeared crenezumab would not meet the primary endpoint of change from baseline in the CDR-SB (Clinical Dementia Rating-Sum of Boxes) score. There were no safety signals raised in the analysis.

The second compound was Biogen and Eisai's aducanumab in two Phase II trials, ENGAGE and EMERGE. Despite having evidence that the compound was hitting the target beta amyloid, the interim data analysis suggested that the study would fail in meeting it's endpoints based on the CDR-SB scores. Again, there were no safety signals raised in the analysis.

A Message from Dr. Goodman

Although the amyloid target has met with disappointing results thus far, there are different areas of attacking amyloid which are being pursued. Another very encouraging target is the second signature protein of Alzheimer's Disease (AD), tau. Although like amyloid in its normal form, tau plays an important role in the brain. When tau misfolds it becomes toxic and instead of supporting brain cells it injures them. Recently we also learned that tau travels from brain cell to brain cell and when it is between the brain cell it can be captured and removed by a monoclonal antibody, the same mechanism as clearing out amyloid which is always outside of the brain cell. Multiple large pharmaceuticals are exploring this new target. At Bioclinica, we are conducting several of these trials. Likewise, some interest is moving away from "pathologic" targets such as amyloid and tau, looking at molecular targets such as brain inflammation. We will be conducting several trials looking at modulating brain inflammation in the near future. In addition, some people feel there is an infectious component to AD and in fact, studies are being developed to target possible infectious agents. All in all, it seems to become obvious that AD is not just a one size fits all disease and that it may have multiple components; genetic predisposition, behavior and environmental inputs, metabolic and medical inputs, as well as a very recent discovery of an important inflammatory component.



COMMUNITY CORNER

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Lewy Body Support Group

2nd Monday of the Month at 4:30pm

Bioclinica Conference Room, 5th Floor

100 W Gore St, 5th Floor, Orlando, FL 32806

Contact for More Info: Sue Boudier 914-589-2004

Memories in the Making, Watercolor Painting

www.alz.org

Alzheimer's & Dementia Resource Center

adrccares.org, 407-436-7750

- Offers classes, support groups, and online tips for caregivers, along with a calendar of events.
- Affiliated with Brain Bank – see website for more information.

Alzheimer's Association

www.alz.org

Alzheimer's Disease and Related Dementias (ADEAR)

National Institute on Aging

www.nia.nih.gov/health/alzheimers



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Current Trial Count

Alzheimer's Disease-

Disease modifying, symptomatic and agitation trials: 10

Preventive (no memory complaints) trials: 2

Parkinson's Disease-

Disease modifying and symptomatic trials: 8

Dementia with Lewy Bodies-

Symptomatic Trial - 1

IDEAS Results Are In

IDEAS was an imaging study funded by Medicare, Pharma, Alzheimer's Association, and American College of Radiology to gather evidence on the influence of amyloid labeling PET scan on diagnosis of Alzheimer's MCI and dementia. Medicare covered their portion of the scan which can cost over \$4,000 for the 16,008 patients who enrolled in the trial from 2016-2017. The amyloid scan helped change diagnoses from Alzheimer's to non-Alzheimer's disease in 25% of cases and altered clinical management in nearly two thirds of all patients. The most common change in clinical management involved the prescribed medications for Alzheimer's disease. For patients with mild cognitive impairment, 43.6% were changed, and with dementia 44.9% had their medications changed based on the result of the scan. Clinical management was significantly influenced with an 85% change. The scan is still not covered by Medicare but there is hope CMS will change their decision based on the data from IDEAS. The scan is FDA approved and available in Central Florida. Other ways to obtain the scan is through the screening process for a clinical drug trial.