A&D Resource Directory

Alzheimer's and Dementia Resource Center of NYC

Newsletter #6 - June 2021

To: Our Friends

From: Ira Asherman

Subject: Aducanumab

The approval by the FDA of Biogen's new drug has created a great number of questions. Among them:

- Why did the drug get approved now?
- Are the clinical trial results conclusive?
- Is the drug safe?
- Are there any side effects?
- Why have people resigned from the FDA advisory committee?
- Has the drug been tested on people with all types of Alzheimer's?
- Does my insurance cover the costs of the drug?

Answering these questions is central to our decision making; to helping us understand the advantages and disadvantages of this drug and answer the question, "Should my loved one take this drug?". The Times summarized the debate in the following terms: "The F.D.A. advisory committee, along with an independent think tank and several prominent experts — including some Alzheimer's doctors who worked on the aducanumab clinical trials — said the evidence raised significant doubts about whether the drug is effective. They also said that even if it could slow cognitive decline in some patients, the benefit suggested by the evidence would be so slight that it would not outweigh the risk of swelling or bleeding in the brain that the drug caused in the trials."

Despite the above the FDA approved the drug explaining their reasons in the following terms: “The data included in the applicant’s submission were highly complex and left residual uncertainties regarding clinical benefit.” However, felt it was important “to provide earlier access to potentially valuable therapies for patients with serious diseases where there is an unmet need, and where there is an expectation of clinical benefit despite some residual uncertainty regarding that benefit.”

To help you fully understand the drugs advantages and potential side effects we have listed several articles and an upcoming presentation by doctors at the University of Pennsylvania.

PRESENTATION

FDA approves Alzheimer's drug Aducanumab: **PMC co-directors to host community forum**. Dr. Wolk and Dr Karlawish, co-directors of the Penn Memory Center, will discuss the FDA's decision on Aducanumab and what it means for the future of clinical care and research at PMC. Questions will be taken at the end of the discussion.

This off-the-record event is intended for PMC patients and their loved ones and is not open to members of the media. Register at: https://pennmedicine.zoom.us/meeting/register/tJ0tcu-oqjIsGNDKHLLTwYbuxRzLqhvKKEOI.

ARTICLES

- **US Against Alzheimer’s** - https://www.usagainstalzheimers.org/. See article on the Home page.
- **Being Patient** - www.beingpatient.com. Check articles on the Home Page.
- **Alzheimer’s association** - https://www.alz.org/alzheimers-dementia/treatments/aducanumab-news.
- **NY Times** - https://www.nytimes.com/2021/06/07/health/aduhelm-fda-alzheimers-drug.html?searchResultPosition=3.

- **Jason Karlawish** – "*If the FDA Approves Biogen's Alzheimer's Treatment, I Won't Prescribe It*" - https://www.statnews.com/2021/05/30/if-the-fda-approves-biogens-alzheimers-treatment-i-wont-prescribe-it/.

Please remember to regularly check the Event Calendar on our website for up-to-date information on events in the NYC area! The link is:

https://adrcnyc.org/event-calendar.htm