President and CEO Update

ALZHEIMER's ASSOCIATION

Update: FDA Requests Additional Data and Extends Review Period

January 29, 2021

This message is sent to all Alzheimer's Association and Alzheimer's Impact Movement board members, all Alzheimer's Association staff, and volunteers and supporters of AIM and the Alzheimer's Association.

This morning, Biogen announced that the FDA has extended the review period for aducanumab by three months, to June 7, 2021. The FDA requested additional data and analyses for its review of the potential treatment for Alzheimer's. The request for the additional data and analyses is considered a Major Amendment to the FDA application, which drives the extended time for review.

As a science-based patient advocacy organization, we are encouraged and appreciate the thoughtful and rigorous review of scientific data and analysis by the FDA.

We believe the publicly released scientific data [*Emphasis added],* the crushing realities faced by individuals and families living with Alzheimer's, and no approved treatment for the underlying disease, support FDA approval of aducanumab, accompanied by a Phase 4 post marketing surveillance study.

If approved, aducanumab would be the first available treatment to potentially change the progression of Alzheimer's, not just the symptoms, for millions of people facing the disease today.

We will continue to advocate, driven by science, on behalf of our constituents. I will continue to share important developments as the FDA pursues their review process. And, I will notify you when they announce a final decision. Of course, no matter the outcome in this case, we remain relentless in our efforts to realize our vision of a world without Alzheimer's. Thank you for everything you do to make that possible.

Harry Johns
Chief Executive Officer