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Peripheral and Central Nervous System Drugs Advisory Committee
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Building 31, Room 2417
Silver Spring, Maryland 20993-0002

October 23, 2020

Re: Docket No. FDA-2018-N-0410: Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

To Members of the Peripheral and Central Nervous System Drugs Advisory Committee,

On behalf of the Alzheimer's Association, all those living with Alzheimer's disease, their caregivers, and their families, we are grateful to the Food and Drug Administration (FDA) for convening this advisory committee and for so carefully weighing this therapeutic agent, which may address the underlying biology of Alzheimer's disease.

For decades, millions of Americans and their loved ones have waited for access to such a therapy as they have faced this relentless disease. Currently, more than 5 million Americans are living with Alzheimer's disease. This number will only grow as our nation ages. By 2050, a projected 13.8 million Americans 65 and older may have Alzheimer's.[1]

As the leading voluntary health organization in Alzheimer's care, support, and research, each year we speak with hundreds of thousands of families through our 24/7 Helpline and serve communities by providing education and support to people living with this disease and their families everyday. We hear from people who are devastated and confused, struggling to process a diagnosis that some doctors still fear to deliver, and from those trying to determine how to continue to function in the face of a progressive, fatal decline. Through our work, we have witnessed firsthand the devastating toll Alzheimer's disease takes on individuals, their caregivers, and families.

While everyone experiences the disease differently, the trajectory of cognitive and functional decline is currently inevitable, and the disease is fatal. For individuals living with Alzheimer's, they lose more of themselves as it progresses. It's not just memories they lose. They lose the

[1] Alzheimer's Association. (2020). *2020 Alzheimer's Disease Facts and Figures.*

ability to participate in the world around them. They lose their independence. All of those affected die with or of Alzheimer's disease.

For the person with the disease, a diagnosis is devastating. But they aren't the only ones affected. For families and friends, watching a once vibrant, curious, and articulate loved one slip away can be heart-wrenching. But on top of the emotional pain, they become caregivers. They take on overwhelming tasks in order to support the person in their daily life, including bathing and dressing, feeding, keeping them safe, and making every single decision for them all day, everyday. And often they do so at great personal expense to their health, economic security, and emotional well-being.

In 2019 alone, caregivers of people with dementia provided an estimated 18.6 billion hours of unpaid assistance. Nearly half of dementia caregivers (49 percent) indicate that providing help is highly stressful compared with 35 percent of caregivers of people without dementia. This disproportionate reporting of stress compared to other caregivers is not surprising. Caring for a person with Alzheimer's poses special challenges. Individuals with Alzheimer's require increasing levels of supervision and personal care as the disease progresses. People in the middle to later stages of Alzheimer's experience losses in judgment, orientation, and the ability to understand and communicate effectively. The personality and behavior of a person with Alzheimer's are affected as well, and these changes are often among the most challenging for family caregivers and can often lead to placement in a long-term care community.

That is why the decision before the members of this committee is so critical. There is a dire and drastic need to offer relief and support to the millions of Americans impacted each day by the crushing realities of Alzheimer's.

Given the devastating toll of this disease, the publicly released data justifies approval accompanied by a Phase 4 post-marketing surveillance study. The alternative, requiring completion of an additional Phase 3 trial, would deny broad access up to four years while it is completed. A four-year delay is too long to wait for millions of Americans facing a progressive, fatal disease. A four-year delay is too long to wait for millions of American caregivers. While the trial data has led to some uncertainty among the scientific community, this must be weighed against the certainty of what this disease will do to millions of Americans absent a treatment. The potential to delay decline would be denied to millions, and that time lost for those spouses, partners, moms, dads, grandmothers, grandfathers, aunts, uncles, friends, and neighbors cannot be recovered. In the balance of these considerations, we urge approval.

Given the potential this therapy may offer, we are grateful for the advisory committee's careful consideration of all evidence and information, and we deeply respect and appreciate the FDA's role in the health and safety of our constituents and its adherence to a rigorous scientific review.

Thank you for the opportunity to comment. The Alzheimer's Association would be glad to serve as a resource to the FDA as it considers aducanumab, future therapies, and any other issue related to Alzheimer's disease and other dementia. Please do not hesitate to contact Laura Thornhill,

Senior Associate Director, Regulatory Affairs, at lthornhill@alz-aim.org or 202.638.7042 if we can be of additional assistance.

Sincerely,

Joanne Pike, DrPH
Chief Strategy Officer