



Food and Drug Administration
10903 New Hampshire Avenue
Building 31, Room 2417
Silver Spring, Maryland 20993-0002

May 23, 2024

Re: Docket No. FDA-2024-N-1869: Advisory Committee Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Biologics License Application 761248 for Donanemab Solution for Intravenous Infusion

Dear Members of the Advisory Committee,

As individuals living with early Alzheimer's disease and mild cognitive impairment, we are grateful for the Food and Drug Administration's and this committee's diligence in evaluating the safety and efficacy of desperately-needed treatments, giving us and our families more hope and precious time.

While we understand that your primary function is to assess the scientific data related to donanemab, our personal experience and the impact this disease has on each of us and our families should be a part of your consideration.

First, we are aware that this and similar treatments will not save our lives. They can, however, give us more time to live — and to live well. To live well means traveling, hiking, cuddling with Maine Coon cats, participating in grandchildren's milestones, and getting to explore a few more months or years of a new marriage. It also means being able to help our families by taking care of our grandkids while our grown children work, and being able to take care of our aging parents as they experience their own decline. More time means being independent for just a bit longer, delaying the inevitable and often tremendous burdens that the disease will bring to our families.

Second, these treatments represent hope, and please do not underestimate what hope can mean in the face of a certain fate. Hope can take the edge off the depression and anxiety that many of us feel about the future and can make the thoughts of what is to come a little more bearable day to day. Rest assured that these treatments, to us, mean more than what the data tell you.

We also ask that you carefully consider what these treatments mean to our care partners. Living with a diagnosis is stressful and frightening; it is stressful and frightening in a different way for those who must plan for life after we're no longer able to comprehend it. A delay in the progression of our diseases means that they are able to remain in the workforce longer, both providing for their own families and remaining

productive members of society. A delay means knowing that they have a little more time to plan for that uncharted future. A delay means that they can continue to live *their* lives well.

Finally, on behalf of those of us who are not candidates for donanemab, we want to express our gratitude to you and to the research community for continuing to explore every possible avenue into the mysteries of all forms of dementia and your aggressive pursuit of the keys that will unlock them. Your actions also represent hope for us, for all those living with the disease, and for the millions who will face it.

Thank you for the opportunity to comment. Please do not hesitate to contact Laura Thornhill, Director, Regulatory Affairs, at lthornhill@alz.org or 202-638-7042 if you have questions or require additional information.

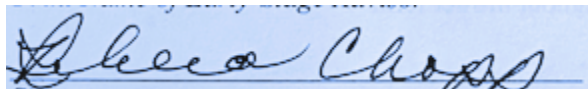
Sincerely,



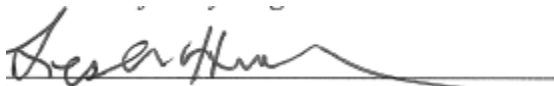
Linda Brewster



Barbara Eades



Rebecca Chopp



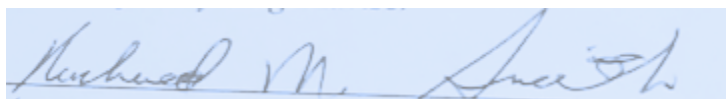
Leslie Henry



Thomas Phillips



Pamela Smith



Richard M. Smith