CRITICAL PATH INSTITUTE

Advocate Sarah Dolan Brings a Patient Voice to FDA Committee Reviewing New Alzheimer's Drug Donanemab

On Monday, June 10, the U.S. Food and Drug Administration's (FDA) Peripheral and Central Nervous System Drugs Advisory Committee voted favorably on the evidence from clinical trials on Eli Lilly's donanemab, a monoclonal antibody designed to slow the progression of early symptomatic Alzheimer's disease — a condition that afflicts more than six million Americans. With no cure currently available and no existing treatments or lifestyle modifications that can restore memory loss or reverse cognitive decline, the committee's unanimous endorsement of donanemab's safety and effectiveness holds significant promise.

C-Path Advisor to CPP Sarah Dolan

Sarah Dolan, who serves as an advisor to Critical Path Institute (C-Path) through its Critical Path for Parkinson's Consortium (CPP), was invited by the FDA to serve as a consumer representative on this FDA Advisory Committee meeting. Dolan's role was pivotal in ensuring the patient perspective was front and center.

In her vote, Dolan expressed satisfaction with the presented evidence, stating, "There's a huge unmet medical need here that hopefully can be addressed."

The FDA will consider the committee's recommendation as part of its regulatory decision regarding donanemab.

Diane Stephenson, Ph.D., Executive Director of CPP, emphasized the critical role of the patient voice, stating, "Patient experiences are increasingly guiding drug developers, a shift driven by the FDA's initiative on patient-focused drug development. Sarah did a fantastic job, drawing from her own experience with a neurological condition and considering the perspective of care partners as well."

C-Path CEO Klaus Romero, M.D., M.S., FCP, praised Dolan's contributions, stating, "We congratulate Sarah on her exemplary service to the FDA Advisory Committee. The value of incorporating a patient and consumer perspective is immeasurable. Sarah's impactful contributions will inspire further progress as C-Path, with nearly 20 years of expertise in addressing unmet needs in Alzheimer's drug development, leverages patient-level data to swiftly develop treatments that significantly improve the lives of those living with Alzheimer's."

As a neutral entity leading public-private partnerships, C-Path brings together diverse stakeholders to identify specific unmet needs in the development of safe and effective therapies for various diseases and generates tools and solutions to help drug developers overcome those barriers.