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Biogen plans regulatory filing for Aducanumab for Alzheimer's

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Biogen and Eisai, Co., Ltd. (Tokyo, Japan) has announced that, after consulting with the U.S. Food and Drug Administration (FDA), Biogen plans to pursue regulatory approval for aducanumab, an investigational treatment for early Alzheimer's disease (AD).

The Phase 3 EMERGE Study met its primary endpoint showing a significant reduction in clinical decline, and Biogen believes that results from a subset of patients in the Phase 3 ENGAGE Study who received sufficient exposure to high dose aducanumab support the findings from EMERGE. Patients who received aducanumab experienced significant benefits on measures of cognition and function such as memory, orientation, and language.

Patients also experienced benefits on activities of daily living including conducting personal finances, performing household chores such as cleaning, shopping, and doing laundry, and independently traveling out of the home. If approved, aducanumab would become the first therapy to reduce the clinical decline of Alzheimer's disease and would also be the first therapy to demonstrate that removing amyloid beta resulted in better clinical outcomes.

The decision to file is based on a new analysis, conducted by Biogen in consultation with the FDA, of a larger dataset from the Phase 3 clinical studies that were discontinued in March 2019 following a futility analysis. This new analysis of a larger dataset that includes additional data that became available after the pre-specified futility analysis shows that aducanumab is pharmacologically and clinically active as determined by dose-dependent effects in reducing brain amyloid and in reducing clinical decline as assessed by the pre-specified primary endpoint Clinical Dementia Rating-Sum of Boxes (CDR-SB). In both studies, the safety and tolerability profile of aducanumab was consistent with prior studies of aducanumab.

"With such a devastating disease that affects tens of millions worldwide, today's announcement is truly heartening in the fight against Alzheimer's. This is the result of groundbreaking research and is a testament to Biogen's steadfast determination to follow the science and do the right thing for patients," said Michel Vounatsos, Chief Executive Officer at Biogen. "We are hopeful about the prospect of offering patients the first therapy to reduce the clinical decline of Alzheimer's disease and the potential implication of these results for similar approaches targeting amyloid beta."

Based on discussions with the FDA, the Company plans to file a Biologics License Application (BLA) in early 2020 and will continue dialogue with regulatory authorities in international markets including Europe and Japan. The BLA submission will include data from the Phase 1/1b studies as well as the complete set of data from the Phase 3 studies.

The Company aims to offer access to aducanumab to eligible patients previously enrolled in the Phase 3 studies, the long-term extension study for the Phase 1b PRIME study, and the EVOLVE safety study. Biogen will work towards this goal with regulatory authorities and principal investigators with a sense of urgency.

After reviewing the data in consultation with the FDA, Biogen believes that the difference between the results of the new analysis of the larger dataset and the outcome predicted by the futility analysis was largely due to patients' greater exposure to high dose aducanumab. Multiple factors contributed to the greater exposure to aducanumab in the new analysis of the larger dataset, including data on a greater number of patients, a longer average duration of exposure to high dose, the timing of protocol amendments that allowed a greater proportion of patients to receive high dose, and the timing and pre-specified criteria of the futility analysis.