Biogen Presents Phase 2 CELIA Data at AAIC Demonstrating Meaningful Clinical Outcomes and Robust Tau Reduction with Diranersen in Early Alzheimer's Disease

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- **Clinical outcomes**: Diranersen demonstrated efficacy across all studied doses at 18 months, with consistent results across multiple prespecified clinical endpoints; the 60 mg dose showed the strongest response with slowing of clinical decline on the cognitive endpoints—42% on ADAS-Cog13 and 50% on MMSE—alongside a 26% slowing on CDR-SE
- **Biomarker response:** Diranersen is the first tau-directed therapy to demonstrate robust reductions in both CSF total tau, with mean reductions of 50–65%, and brain tau pathology, as measured by PET, across all studied doses in a Phase 2 study
- **Dose response:** CDR-SB results favored diranersen versus placebo across all studied doses; higher doses were not associated with greater slowing of decline
- **Mechanism of action:** Distinct from other tau-lowering approaches, diranersen targets MAPT mRNA to reduce the production of all tau isoforms, lowering both intracellular and extracellular tau protein

CAMBRIDGE, Mass., July 14, 2026 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced data from the Phase 2 CELIA study evaluating diranersen, an investigational antisense oligonucleotide (ASO) therapy targeting tau, in individuals with early Alzheimer's disease. The data, presented at the Alzheimer's Association International Conference (AAIC) 2026, expand upon previously reported topline results and demonstrate a combination of meaningful clinical efficacy and robust biomarker effects, providing Phase 2 proof of concept for diranersen's tau-directed mechanism of action. Based on the growing and consistent body of evidence from the Phase 1b and Phase 2 studies, Biogen plans to advance diranersen into confirmatory Phase 3 development.[1]

"The CELIA data provide some of the clearest evidence that reducing tau pathology can translate into clinically meaningful benefit," said Professor Cath Mummery, Professor of Clinical Neurology at the UCL Queen Square Institute of Neurology and Consultant Neurologist at University College London Hospitals NHS Foundation Trust. "The magnitude of tau reduction and cognitive benefit observed in CELIA is among the most compelling reported to date in Alzheimer's disease drug development and supports advancing diranersen to Phase 3 development."

"The CELIA clinical, biomarker, and safety data presented at AAIC provide proof of concept and important evidence of diranersen's novel tau-reduction mechanism of action translating into clinical benefit. If confirmed in Phase 3, diranersen could represent an important new therapeutic approach targeting one of the core pathologies of Alzheimer's disease," said Priya Singhal, M.D., M.P.H., Executive Vice President and Head of Development at Biogen. "Patients and families urgently need new approaches that address the complexity of Alzheimer's disease. We look forward to working with health authorities and the broader Alzheimer's community as diranersen advances to Phase 3."

Diranersen demonstrated efficacy across all studied doses at 18 months, with consistent efficacy across multiple prespecified secondary endpoints, including the Clinical Dementia Rating Sum of Boxes (CDR-SB), a global measure of cognition and daily function; ADAS-Cog13 and MMSE, measures of cognition; modified iADRS and ADCOMS, composite measures of cognition, function, and disease progression; as well as the individual cognitive and functional domains of CDR-SB. Diranersen 60 mg administered intrathecally every six months (n=60) showed the strongest response at 18 months. Compared with placebo (n=115), diranersen 60 mg demonstrated slowing of clinical decline by 0.54 points (26%) on CDR-SB; 42% on ADAS-Cog13; 50% on MMSE; 30% on modified iADRS; and 23% on ADCOMS. The majority of these endpoint differences achieved nominal statistical significance compared with placebo.

Clinical effects were also observed in the other studied dose regimens. Compared with placebo, diranersen 115 mg administered intrathecally every six months (n=115) and diranersen 115 mg administered intrathecally every three months (n=116) demonstrated slowing of clinical decline by 0.28 and 0.18 points (14% and 9%) on CDR-SB; 32% and 29% on ADAS-Cog13; 34% and 38% on MMSE; 29% and 18% on modified iADRS; and 21% and 7% on ADCOMS, respectively. At 18 months, no separation from placebo was observed across dose groups on ADCS-ADL-MCI, a measure of daily functioning, and longer-term follow-up continues to assess whether a longer duration of diranersen therapy impacts this endpoint. Of note, while ADCS-ADL-MCI results were inconsistent across dose regimens, slowing of functional decline based on the functional domains of CDR-SB favored diranersen across all studied doses.

CELIA was designed with a primary endpoint of dose response on CDR-SB at 18 months to investigate whether higher doses of diranersen could provide greater clinical benefit. As previously disclosed, this was not observed, and the study did not meet its primary endpoint.

Diranersen demonstrated target engagement and robust reductions in cerebrospinal fluid (CSF) total tau across all studied doses, with mean reductions of 50–65% from baseline. In the tau PET imaging substudy (n=131), decreases from baseline were seen across all evaluated brain regions for all diranersen doses. Diranersen is the first tau-directed therapy to demonstrate reductions in both CSF total tau and brain tau pathology, as measured by PET, across all studied doses in a Phase 2 study.

Diranersen was generally well tolerated. During the placebo-controlled period, most participants who experienced adverse events had events that were mild or moderate in severity, non-serious, and did not result in treatment discontinuation or study withdrawal. The most frequent adverse events were procedural pain, post-lumbar puncture syndrome, and confusional state. Most adverse events of confusional state occurred within a few days of dosing and resolved within a week. Among participants who completed the placebo-controlled period, more than 90% elected to continue into the extension study. Amyloid-related imaging abnormalities (ARIA) are not anticipated with diranersen based on its tau-targeting mechanism of action, and the results from CELIA are consistent with that expectation.

The study enrolled a population representative of early Alzheimer's disease, with baseline characteristics generally balanced across treatment groups. Participants had a mean age of 68 years, 51% were female, and 60% were classified as having mild cognitive impairment, with 40% having mild Alzheimer's disease dementia. ApoE4 carriers represented approximately 69% of participants, including 23% homozygotes.

Additional analyses and data from CELIA and the ongoing long-term extension study will be presented at future scientific conferences.

A Media Snippet accompanying this announcement is available by clicking on this link.

Educational Program on Tau in Alzheimer's Disease
At AAIC, Biogen is hosting an interactive booth offering an immersive journey into the role of tau in Alzheimer's disease, from pathology to clinical presentation. Biogen is also expanding its educational efforts with a new e-learning module on KnowTau.com, building on the resources already available.

For more information, please see the AAIC 2026 program and visit the Biogen AAIC booth.

About diranersen (BIIB080)
Diranersen (BIIB080) is an investigational antisense oligonucleotide (ASO) therapy designed to target microtubule-associated protein tau (MAPT) mRNA to reduce the production of tau protein. Unlike many investigational approaches that have focused on targeting extracellular tau, diranersen is designed to reduce both intracellular and extracellular tau.

Diranersen is being investigated as a potential treatment for early Alzheimer's disease. In 2025, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to diranersen for the treatment of Alzheimer's disease.

In December 2019, Biogen exercised a license option with Ionis Pharmaceuticals and obtained a worldwide, exclusive, royalty-bearing license to develop and commercialize diranersen. Diranersen was discovered by Ionis.

About the CELIA Study
CELIA is a global Phase 2 randomized, double-blind, placebo-controlled, dose-ranging study evaluating the efficacy, safety, and tolerability of diranersen in individuals with early Alzheimer's disease. The study enrolled 416 participants with mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease dementia. All participants enrolled in CELIA had not previously received anti-amyloid therapy.

The study evaluated three doses of diranersen administered intrathecally over an 18-month placebo-controlled treatment period: 60 mg every six months, 115 mg every six months, and 115 mg every three months.

The primary endpoint of CELIA was assessment of dose response for change from baseline on the Clinical Dementia Rating–Sum of Boxes (CDR-SB) at Week 76. Secondary and exploratory endpoints included additional clinical, biomarker, and imaging measures, including cerebrospinal fluid tau biomarkers and tau positron emission tomography (PET). Additional information on the study design is available in the ClinicalTrials.gov listing for the CELIA study.

An ongoing long-term extension (LTE) study is continuing to evaluate the long-term safety, tolerability, and durability of diranersen's clinical benefit in early Alzheimer's disease.

About Biogen
Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Facebook, LinkedIn, X, YouTube.

Biogen Safe Harbor
This news release contains forward-looking statements, including, among others, relating to: the potential benefits, efficacy and safety of diranersen; the potential that, if confirmed in Phase 3, diranersen could represent a new therapeutic approach targeting one of the core pathologies of Alzheimer's disease; potential regulatory discussions, submissions, decisions and approvals and the timing thereof; the anticipated benefits, risks and potential of our collaboration arrangements; the potential of our commercial business and pipeline programs, including diranersen; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "estimate," "expect," "forecast," "goal," "guidance," "hope," "intend," "may," "objective," "outlook," "plan," "possible," "potential," "predict," "project," "prospect," "should," "target," "will," "would" or the negative of these words or other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements. Given their forward-looking nature, these statements involve substantial risks and uncertainties that may be based on inaccurate assumptions and could cause actual results to differ materially from those reflected in such statements.

These forward-looking statements are based on management's current beliefs and assumptions and on information currently available to management. Given their nature, we cannot assure that any outcome expressed in these forward-looking statements will be realized in whole or in part. We caution that these statements are subject to risks and uncertainties, many of which are outside of our control and could cause future events or results to differ materially from those stated or implied in this document, including, among others, uncertainty of our long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; expectations, plans, prospects and timing of actions relating to product approvals, approvals of additional indications for our existing products, sales, pricing, growth, reimbursement and launch of our marketed and pipeline products; the potential impact of increased product competition in the biopharmaceutical and healthcare industry, as well as any other markets in which we compete, including increased competition from new originator therapies, generics, prodrugs and biosimilars of existing products and products approved under abbreviated regulatory pathways; our ability to effectively implement our corporate strategy; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; the drivers for growing our business, including our dependence on collaborators and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; risks related to commercialization of biosimilars, which is subject to such risks related to our reliance on third-parties, intellectual property, competitive and market challenges and regulatory compliance; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; and the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; and any other risks and uncertainties that are described in reports we have filed with the U.S. Securities and Exchange Commission, which are available on the SEC's website at www.sec.gov.

These statements speak only as of the date of this press release and are based on information and estimates available to us at this time.

Should known or unknown risks or uncertainties materialize or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. Investors are cautioned not to put undue reliance on forward-looking statements. A further list and description of risks, uncertainties and other matters can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025 and in our subsequent reports on Form 10-Q. Except as required by law, we do not undertake any obligation to publicly update any forward-looking statements whether as a result of any new information, future events, changed circumstances or otherwise.

Digital Media Disclosure
From time to time we have used, or expect in the future to use, our investor relations website (investors.biogen.com), the Biogen LinkedIn account (linkedin.com/company/biogen-) and the Biogen X account (https://x.com/biogen) as a means of disclosing information to the public in a broad, non-exclusionary manner, including for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Accordingly, investors should monitor our investor relations website and this social media channel in addition to our press releases, SEC filings, public conference calls and webcasts, as the information posted on them could be material to investors.

Reference:

1. Shulman M, Wu S, Ziogas N, et al. Exploratory analyses of clinical outcomes from the BIIB080 phase 1b study in mild Alzheimer's disease. *Nature Aging*. 2026;6:445-453. https://doi.org/10.1038/s43587-025-01031-9. Accessed July 2026.

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