Biogen's Diranersen Demonstrates Increasing Clinical Benefit at Two Years in Early Alzheimer's Disease

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- Diranersen slowed clinical decline by 38% on CDR-SB at two years (Week 96) with the 60 mg twice-yearly regimen, corresponding to a 1.09-point treatment difference
- Greater slowing of clinical decline across 5 of 6 measures at two years compared with 18 months (Week 76) in the 60 mg dose group
- Clinical benefits were observed across all doses studied, with the 60 mg dose group showing compelling efficacy and a favorable benefit-risk profile
- Data presented at the Clinical Trials on Alzheimer's Disease (CTAD) conference

CAMBRIDGE, Mass., Nov. 17, 2026 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced new data from the Phase 2 CELIA study showing increasing clinical benefit of diranersen, an investigational antisense oligonucleotide (ASO) therapy targeting tau, in people living with early Alzheimer's disease at two years (Week 96). Results presented at the Clinical Trials on Alzheimer's Disease (CTAD) 2026 conference showed slowing of clinical decline across measures of cognition, function and disease progression, with the 60 mg twice-yearly regimen showing the largest treatment effects at two years.

"The two-year data presented at CTAD mark an important milestone for diranersen, demonstrating not only sustained clinical benefit but also an increasing magnitude of effect at two years," said Priya Singhal, M.D., M.P.H., Executive Vice President and Head of Development at Biogen. "These findings strengthen the growing body of evidence supporting tau as a therapeutic target and underscore the potential of diranersen to meaningfully impact disease progression for people living with early Alzheimer's disease."

"These are highly encouraging results, particularly given the progressive nature of Alzheimer's disease," said Lawren VandeVrede, M.D., Ph.D., a principal investigator in the Phase 2 CELIA study at the University of California, San Francisco. "The increasing separation observed between 18 months and two years is remarkable and clinically meaningful. For patients and families, slowing clinical decline means more time in early stages, preserving independence, and remaining connected to the people and experiences that matter most."

At two years, analyses showed that diranersen continued to slow clinical decline across measures of cognition, function and disease progression. Clinical benefits were observed across all doses studied, with the 60 mg twice-yearly regimen showing the largest treatment effects at two years. Diranersen was generally well tolerated through two years, with no new safety signals observed.

Clinical outcomes with the 60 mg twice-yearly regimen (n=60) versus participants originally randomized to placebo (n=115)	**Week 76**	**Week 96**
CDR-SB	26%	38%*
ADAS-Cog13	42%	54%
MMSE	50%	38%
ADCS-ADL-MCI	0%	30%
ADCOMS	23%	38%
Modified iADRS	30%	46%

* Corresponding to a 1.09-point treatment difference on CDR-SB at Week 96

The two-year analyses were derived from the ongoing open-label extension phase of CELIA. Treatment effects were calculated by comparing participants who received diranersen during the placebo-controlled phase of the study and remained on the same dose through two years with participants who were initially assigned to placebo and transitioned into the extension phase. At Week 96, participants in the placebo group had received either no doses or a single dose of diranersen following their transition into the extension phase, providing a placebo-equivalent comparator. All participants in the extension phase are expected to receive diranersen as the study progresses.

Alongside the two-year results, Biogen presented new 18-month placebo-controlled clinical and biomarker findings from CELIA that further support the effects of diranersen. At 18 months, the twice-yearly 60 mg diranersen sub-group analysis showed preferential efficacy in memory, orientation, and executive function. Diranersen also robustly reduced tau PET signal broadly across the brain, CSF p-tau181, and plasma p-tau217.

These data build on previously reported results from the Phase 2 CELIA study and further support the continued development of diranersen for people living with early Alzheimer's disease.

Frequently Asked Questions

1. What do the two-year data show?
At two years, CELIA showed slowing of clinical decline across measures of cognition, function and disease progression. With the 60 mg twice-yearly regimen, clinical benefit increased over time and was largest at two years. Treatment effects increased from 26% to 38% on CDR-SB, from 42% to 54% on ADAS-Cog13, from 0% to 30% on ADCS-ADL-MCI, from 23% to 38% on ADCOMS and from 30% to 46% on modified iADRS. Together, these findings show a greater magnitude of clinical benefit at two years compared with 18 months.

2. How should we interpret the clinical benefit observed at two years?
With the 60 mg twice-yearly regimen, participants demonstrated a 1.09-point treatment difference on the Clinical Dementia Rating Scale Sum of Boxes (CDR-SB). A one-point difference on CDR-SB is generally considered highly meaningful by clinicians, and the clinical benefit observed with diranersen in CELIA surpassed that threshold at two years.

3. What do these findings mean for people living with early Alzheimer's disease and their families?
The two-year results from CELIA provide encouraging evidence that diranersen has the potential to slow clinical decline in people with early Alzheimer's disease. These Phase 2 findings support the continued development of diranersen and further evaluation in a Phase 3 trial designed to confirm its efficacy and safety. However, diranersen remains an investigational therapy and has not been approved by any regulatory authority.

4. Why is the 60 mg twice-yearly regimen important?
Clinical benefits were observed across all doses studied in CELIA, with the 60 mg twice-yearly regimen demonstrating compelling efficacy and a favorable benefit-risk profile, supporting its continued development.

5. Why is tau an important target in Alzheimer's disease, and how does diranersen work?
Tau is one of the core pathologies of Alzheimer's disease and is closely associated with disease progression and cognitive decline. Diranersen is an investigational antisense oligonucleotide, or ASO, designed to target MAPT mRNA and reduce the production of all tau isoforms, lowering both intracellular and extracellular tau. The CELIA results add to the growing body of evidence supporting tau as an important therapeutic target and provide further evidence that this novel mechanism may translate into meaningful clinical benefit.

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 clinical effects of diranersen; the clinical development program, clinical trials, data readouts and presentations related to diranersen; the treatment of Alzheimer's disease and the relation between tau protein and Alzheimer's disease; 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
We use and 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 material nonpublic information to the public in a broad, non-exclusionary manner, including for purposes of complying with our obligations under 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.

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