Biogen and Stoke Therapeutics Announce Presentations at the 2025 American Epilepsy Society Annual Meeting

December 1, 2025

New analyses from the ongoing open label extension (OLE) studies and findings from electroencephalogram (EEG) assessments in patients with Dravet syndrome treated with zorevunersen support the potential for disease modification

CAMBRIDGE, Mass and BEDFORD, Mass., Dec. 01, 2025 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) and Stoke Therapeutics, Inc. (Nasdaq: STOK), a biotechnology company dedicated to restoring protein expression by harnessing the body's potential with RNA medicine, today announced data presentations from studies of zorevunersen at the 2025 American Epilepsy Society (AES) Annual Meeting, taking place December 5-9 in Atlanta, Georgia.

Zorevunersen is an investigational antisense oligonucleotide currently being evaluated as a potential first-in-class medicine for the treatment of Dravet syndrome, a severe developmental and epileptic encephalopathy (DEE) characterized by recurrent seizures and significant cognitive and behavioral impairments. Data to be presented at AES are derived from four years of clinical data from the Phase 1/2a and ongoing OLE studies of zorevunersen and will include new propensity weighted analyses. Zorevunersen is also currently being evaluated in the global, pivotal Phase 3 EMPEROR study in children and adolescents with Dravet syndrome.

"Our four years of data showing substantial and durable effects on seizures, behavior and cognition, combined with our ability to compare directly to natural history data, allow us to more fully appreciate the disease-modifying potential of zorevunersen for the treatment of Dravet syndrome," said Barry Ticho, M.D., Ph.D., Chief Medical Officer of Stoke Therapeutics. "We look forward to discussing our latest findings with the world's leading epilepsy experts at AES."

"The new EEG data at AES highlight the effects of zorevunersen in decreasing abnormal brain activity that is persistently higher in patients with Dravet syndrome," said Katherine Dawson, M.D., Head of the Therapeutics Development Unit at Biogen. "In patients treated with zorevunersen, exploratory analyses showed that a reduction in abnormal brain EEG activity was associated with an increased probability of achieving a reduction in major motor seizure frequency. These findings, in addition to the clinical data to be presented, show the potential effect of zorevunersen on the underlying disease in patients with Dravet syndrome."

Details of the presentations at AES are as follows:

- **Title:** Zorevunersen Continues to Demonstrate Potential as a Disease-modifying Therapy in Long-term Open-label Extension Studies of Patients with Dravet Syndrome

Oral Presentation Date & Time: Friday, December 5, 3:30-5:55 PM EST
Oral Presenter: M. Scott Perry, M.D., Head of Neurosciences and Director of the Jane and John Justin Institute for Mind Health and Medical Director of Neurology at the Genetic Epilepsy Clinic at Cook Children's

- **Title:** Zorevunersen Demonstrates Disease-modifying Potential in Patients with Dravet Syndrome with Increases in Seizure-free Days, Improvements in Quality of Life, and Benefits in Overall Functioning

Poster Presentation Date & Time: Saturday, December 6, 12:00-2:00 PM EST
Poster Presenter: Kelly Knupp, M.D., MSCS, Professor of Pediatrics and Neurology at the University of Colorado Anschutz and the Dravet Program Director and Epilepsy Program Lead at Children's Hospital Colorado
Poster Number: 1.379

- **Title:** Electrophysiological Improvements in Patients with Dravet Syndrome Following Treatment with Zorevunersen, an Investigational Antisense Oligonucleotide

Poster Presentation Date & Time: Monday, December 8, 12:00-1:45 PM EST
Poster Presenter: Nigel Colenbier, Senior Data Scientist, Epilog, Clouds of Care
Poster Number: 3.489

- **Title:** Spectral Electroencephalogram Abnormalities Across Development in Patients with Dravet Syndrome

Poster Presentation Date & Time: Sunday, December 7, 12:00-2:00 PM EST
Poster Presenter: Pieter van Mierlo, Founder and Chief Scientific Officer, Epilog, Clouds of Care, Associate Professor, Ghent University
Poster Number: 2.432

About Dravet Syndrome
Dravet syndrome is a severe developmental and epileptic encephalopathy (DEE) characterized by recurrent seizures as well as significant cognitive and behavioral impairments. Most cases of Dravet are caused by mutations in one copy of the *SCN1A* gene, leading to insufficient levels of NaV1.1 protein in neuronal cells in the brain. Even when treated with the best available anti-seizure medicines (ASMs), up to 57 percent of patients with Dravet syndrome do not achieve ≥50 percent reduction in seizure frequency. Complications of the disease often contribute to a poor quality of life for patients

and their caregivers. Developmental and cognitive impairments often include intellectual disability, developmental delays, movement and balance issues, language and speech disturbances, growth defects, sleep abnormalities, disruptions of the autonomic nervous system and mood disorders. Compared with the general epilepsy population, people living with Dravet syndrome have a higher risk of sudden unexpected death in epilepsy, or SUDEP; up to 20 percent of children and adolescents with Dravet syndrome die before adulthood due to SUDEP, prolonged seizures, seizure-related accidents or infections[1]. Dravet syndrome occurs globally and is not concentrated in a particular geographic area or ethnic group. Currently, it is estimated that up to 38,000 people are living with Dravet syndrome in the U.S. (~16,000), UK, EU-4 and Japan[2]. There are no approved disease-modifying therapies for people living with Dravet syndrome.

About Zorevunersen
Zorevunersen is an investigational antisense oligonucleotide that is designed to treat the underlying cause of Dravet syndrome by increasing functional NaV1.1 protein production in brain cells from the non-mutated (wild-type) copy of the SCN1A gene. This highly differentiated mechanism of action aims to reduce seizure frequency beyond what has been achieved with anti-seizure medicines and to improve neurodevelopment, cognition, and behavior. Zorevunersen has demonstrated the potential for disease modification and has been granted orphan drug designation by the FDA and the EMA. The FDA has also granted zorevunersen rare pediatric disease designation and Breakthrough Therapy Designation for the treatment of Dravet syndrome with a confirmed mutation not associated with gain-of-function, in the SCN1A gene. Stoke has a strategic collaboration with Biogen to develop and commercialize zorevunersen for Dravet syndrome. Under the collaboration, Stoke retains exclusive rights for zorevunersen in the United States, Canada, and Mexico; Biogen receives exclusive rest of world commercialization rights.

About the EMPEROR Study
The EMPEROR Phase 3 Study (NCT06872125) is a global, double-blind, sham-controlled study evaluating the efficacy, safety, and tolerability of zorevunersen in children ages 2 to <18 with Dravet syndrome with a confirmed variant in the SCN1A gene not associated with gain-of-function. The trial is expected to enroll participants across the United States, Japan, United Kingdom and European Union, with participants being randomized 1:1 to receive either zorevunersen via intrathecal administration or a sham comparator for a 52-week treatment period following an 8-week baseline period. Following the completion of the study, eligible participants will be offered ongoing treatment with zorevunersen as part of an OLE study. The primary endpoint of the study is percent change from baseline in major motor seizure frequency at week 28 in patients receiving zorevunersen as compared to sham. The key secondary endpoints are the durability of effect on major motor seizure frequency and improvements in behavior and cognition as measured by Vineland-3 subdomains, including expressive communication, receptive communication, interpersonal relationships, coping skills and personal skills. Additional endpoints include safety, Clinician Global Impression of Change (CGI-C), Caregiver Global Impression of Change (CaGI-C), and the Bayley Scales of Infant Development (BSID-IV). For more information, visit https://www.emperorstudy.com/.

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.

About Stoke Therapeutics
Stoke Therapeutics (Nasdaq: STOK), is a biotechnology company dedicated to restoring protein expression by harnessing the body's potential with RNA medicine. Using Stoke's proprietary TANGO (Targeted Augmentation of Nuclear Gene Output) approach, Stoke is developing antisense oligonucleotides (ASOs) to selectively restore naturally-occurring protein levels. Stoke's first medicine in development, zorevunersen, has demonstrated the potential for disease modification in patients with Dravet syndrome and is currently being evaluated in a Phase 3 study. Stoke's initial focus are diseases of the central nervous system and the eye that are caused by a loss of ~50% of normal protein levels (haploinsufficiency). Proof of concept has been demonstrated in other organs, tissues, and systems, supporting broad potential for Stoke's proprietary approach. Stoke is headquartered in Bedford, Massachusetts. For more information, visit https://www.stoketherapeutics.com/.

Biogen Safe Harbor
This news release contains forward-looking statements relating to, among others: the potential clinical effects of zorevunersen; the potential of zorevunersen to improve the health, wellbeing and outcomes for patients with Dravet syndrome; the potential benefits, safety and efficacy of zorevunersen; potential regulatory discussions, submissions and approvals and the timing thereof; the treatment of Dravet syndrome; the anticipated benefits, risks and potential of Biogen's collaboration arrangements with Stoke; the potential of Biogen's commercial business and pipeline programs, including zorevunersen; 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 other 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, 2024 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 these social media channels in addition to our press releases, SEC filings, public conference calls and websites, as the information posted on them could be material to investors.

Stoke Therapeutics Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, the ability of zorevunersen to treat the underlying causes of Dravet syndrome and reduce seizures or show improvements in behavior and cognition at the indicated dosing levels or at all, the timing and expected progress of clinical trials, data readouts, regulatory meetings, regulatory decisions and other presentations, and the participation of scientists associated with Stoke making presentations at the 2025 AES Annual Meeting and the presentation of data at the 2025 AES Annual Meeting. Statements including words such as "plan," "potential," "will," "continue," "expect," or similar words and statements in the future tense are forward-looking statements. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they prove incorrect or do not fully materialize, could cause Stoke's results to differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, risks and uncertainties related to: Stokes ability to advance, obtain regulatory approval and ultimately commercialize its product candidates; that if Biogen were to breach or terminate the collaboration, Stoke would not obtain the anticipated financial or other benefits; the possibility that Stoke and Biogen may not be successful in their development of zorevunersen and that, even if successful, they may be unable to successfully commercialize zorevunersen; positive results in a clinical trial may not be replicated in subsequent trials or successes in early stage clinical trials may not be predictive of results in later stage trials; Stoke's ability to protect its intellectual property; Stoke's ability to fund development activities and achieve development goals to mid-2028; and the other risks and uncertainties described under the heading "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2024, its quarterly reports on Form 10-Q, and the other documents it files with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release, and Stoke undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

References:

1. Symonds, J. et al. Early childhood epilepsies: epidemiology, classification, aetiology, and socio-economic determinants. *Brain.* 2021;144(9):2879-2891.
2. Based on Stoke Therapeutics' preliminary estimates, which scaled annual incidence to prevalence using country-specific live birth rates over the past 85 years and adjusted for Dravet-specific mortality. The estimate is based on incidence rates published by Wu et al., Pediatrics, 2015.

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