Biogen to Share New SMA Data at Muscular Dystrophy Association and SMA Europe Conferences

March 5, 2026

- Long-term data from DEVOTE/ONWARD studies show benefits of high dose nusinersen in people living with spinal muscular atrophy (SMA)
- New Phase 1b data further illustrate potential of salanersen in SMA, as Phase 3 studies begin to evaluate this investigational drug that has the potential for high potency with once-yearly dosing

CAMBRIDGE, Mass., March 05, 2026 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) – will present new data and updates from its spinal muscle atrophy (SMA) research programs, including high dose nusinersen and salanersen, at the 2026 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference (March 8-11, 2026) and 5th International Scientific Congress on SMA (SMA Europe 2026; March 11-14, 2026).

“Over the past decade, we have remained steadfast in our pursuit of scientific innovation to support the evolving efficacy needs of the SMA community. We are at an important juncture for our SMA portfolio as we look to bring the high dose regimen of nusinersen to the community and advance salanersen into registrational studies,” said Stephanie Fradette, Pharm,D., Head of the Neuromuscular Development Unit at Biogen. “We are excited to share new longer-term data on high dose nusinersen and salanersen, cross-study neurofilament data, and the design of our salanersen Phase 3 studies.”

Highlights of Biogen’s SMA Data Presented at MDA and SMA Europe

Nusinersen

- Exploring Higher Doses of Nusinersen in Spinal Muscular Atrophy (SMA): Integrated Results from the DEVOTE Part B and ONWARD Studies
  - MDA: *Poster 101S – Sunday, 8 March – 6:00-8:00 pm ET*
  - SMA Europe: *P69 – Thursday, 12 March – 4:15-530 pm CEST*
- DEVOTE Part C and ONWARD Integrated Results: Higher Doses of Nusinersen in Nusinersen-Experienced Participants with Spinal Muscular Atrophy (SMA)
  - MDA: *Florida 4 - Wednesday, 11 March – 8:15 am ET*
  - SMA Europe: *P70 – Friday, 13 March – 4:15-530 pm CEST*

Salanersen

- STELLAR Phase 3 Studies to Evaluate the Efficacy and Safety of Salanersen in Infants with Spinal Muscular Atrophy (SMA)
  - MDA: *Poster 199M - Monday, 9 March – 6:00 – 8:00 pm ET*
  - SMA Europe: *P72 – Thursday, 12 March – 4:15 – 530 pm CEST*
- The SOLAR study: Phase 3 Study to Evaluate the Efficacy and Safety of Salanersen in Participants Aged 15–60 Years with Spinal Muscular Atrophy (SMA)
  - MDA: *Poster 193M - Monday, 9 March 6:00 – 8:00 pm ET*
  - SMA Europe: *P67 – Thursday, 12 March – 4:15-530 pm CEST*
- Phase 1 Interim Results Evaluating the Safety, Tolerability, Pharmacokinetics, and Exploratory Efficacy of Salanersen for Spinal Muscular Atrophy
  - MDA: *Florida 4 - Wednesday, 11 March – 8:00 am ET*
  - SMA Europe: *P71 – Thursday, 12 March – 4:15-530 pm CEST*

MDA Only

- Neurofilament Light Chain as a Biomarker in Spinal Muscular Atrophy
  - *Poster 195M - Monday, 9 March 6:00 – 8:00 pm ET*

DEVOTE is a Phase 2/3 study that examined the clinical efficacy, safety and tolerability of high dose nusinersen in SMA. ONWARD is a Phase 3 long-term extension for those who previously participated in the DEVOTE study, primarily assessing long-term safety. The high dose regimen of nusinersen, known as SPINRAZA, is also approved in Japan, the European Union, and Switzerland, and is under review with the U.S. Food and Drug Administration (FDA) with a decision expected by April 3, 2026 and other geographies around the world. Biogen is working with regulatory authorities around the world to progress this additional dosing option for people living with SMA.

Biogen licensed the global development, manufacturing and commercialization rights for salanersen from Ionis Pharmaceuticals, Inc. Salanersen was discovered by Ionis.

About SPINRAZA
The high dose regimen of SPINRAZA (nusinersen) comprising a 50 mg/5 mL loading dose and 28 mg/5 mL maintenance dose injections is currently approved in the European Union, Japan, and Switzerland to treat infants, children and adults with spinal muscular atrophy (SMA).

The low dose regimen of SPINRAZA comprising 12 mg/5 mL injection is approved for SMA in more than 71 countries.[1] It has shown efficacy across ages and SMA types with a well-established safety profile based on data in patients treated up to 10 years,[2,3] combined with unsurpassed real-world experience. The most common adverse events observed in clinical studies were respiratory infection, fever, constipation, headache, vomiting and back pain. Laboratory tests can monitor for renal toxicity and coagulation abnormalities, including acute severe low platelet counts, which have been observed after administration of some ASOs.

Biogen licensed the global rights to develop, manufacture and commercialize SPINRAZA from Ionis Pharmaceuticals, Inc. (Nasdaq: IONS). Please click here for Important Safety Information and full Prescribing Information.

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, Instagram, 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 a High Dose Regimen of nusinersen (SPINRAZA) and salanersen; the potential to advance care and improve outcomes for, and address unmet needs of, patients with SMA; 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 Biogen's SMA research programs; 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.

References:

1. Based on commercial patients, early access patients, and clinical trial participants through December 31, 2024.
2. Core Data sheet, Version 13, October 2021. SPINRAZA. Biogen Inc, Cambridge, MA.
3. Finkel et al. Cure SMA 2024. "Final Safety and Efficacy Data From the SHINE Study in Participants With Infantile-Onset and Later-Onset SMA."

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