Biogen to Present New Late-Breaking Litifilimab Phase 2 AMETHYST Data in Cutaneous Lupus Erythematosus at 2026 American Academy of Dermatology Annual Meeting

March 19, 2026

- Late-breaking AMETHYST Part A study results to be presented, showing safety and efficacy of litifilimab in cutaneous lupus erythematosus (CLE)
- Litifilimab was recently granted Breakthrough Therapy Designation by the FDA for CLE; AMETHYST Part A results supported the designation
- CLE is a serious autoimmune disease that impacts the daily lives of patients and can lead to permanent scarring and disfigurement when left untreated, and has no targeted treatment option

CAMBRIDGE, Mass., March 19, 2026 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced upcoming scientific presentations at the 2026 American Academy of Dermatology (AAD) Annual Meeting, taking place March 27-31. Late-breaking data from Part A (Phase 2) of the AMETHYST Phase 2/3 study will be presented that highlight litifilimab's effect on cutaneous lupus erythematosus (CLE) disease activity. Litifilimab is a potential first in-class, monoclonal antibody (mAb) targeting blood dendritic cell antigen 2 (BDCA2) and was the first investigational therapy to show positive results in CLE, as shown in the Phase 2 LILAC study. Additional presentations at AAD will provide new insights into measures used to assess the severity of CLE disease activity in both clinical trials and clinical practice.

"The data we are presenting at AAD reflect Biogen's decades of investment in cutaneous lupus, a disease that extends far beyond the skin, significantly impacting the daily lives and mental health of people living with this disease, and often leading to permanent scarring," said Diana Gallagher, MD, Senior Vice President and Head of AD, MS and Immunology Development Units at Biogen. "We look forward to sharing the Phase 2 results from AMETHYST that show the potential of litifilimab in CLE. The Phase 3 part of the study, which will further evaluate litifilimab in CLE, is on track and a data readout is expected in 2027."

Earlier this year, the U.S. Food and Drug Administration granted litifilimab Breakthrough Therapy Designation for CLE. Results from the Phase 2 (Part A) part of the AMETHYST study supported the designation, in addition to the previously presented Phase 2 LILAC study results.

Details of the presentations at AAD are as follows:

Late-Breaking Oral Presentation

- "Efficacy and Safety of Litifilimab in Cutaneous Lupus Erythematosus (CLE): 24-week results of the Phase 2 Study, AMETHYST Part A" to be presented Saturday, March 28 3:24 PM MT / 5:24 PM ET in Bellco Theatre 3; #79781

Key Posters

- "A Qualitative Study to Support the Content Validity of the Cutaneous Lupus Activity Investigator's Global Assessment—Revised (CLA-IGA-R): Clinician Perspectives" on display throughout meeting in Poster Exhibits Center; #71096
- "Correlation Between CLASI and CLA-IGA-R Among Patients With CLE in a Multi-Center Cross-Sectional Study in the US" on display throughout meeting in Poster Exhibits Center; #75155

About AMETHYST
AMETHYST is a two-part, Phase 2/3 multicenter, double-blind, placebo controlled, randomized study to evaluate the efficacy and safety of litifilimab compared to placebo. The study aims to assess the efficacy of litifilimab in participants with active subacute cutaneous lupus erythematosus (SCLE) and/or chronic cutaneous lupus erythematosus (CCLE) who are refractory or intolerant to antimalarial therapy. The Phase 2 and Phase 3 parts of the study will each be 52 weeks in duration. Participants will be randomized to receive subcutaneous treatment with litifilimab or placebo every four weeks for 20 weeks with an additional dose at Week 2. All participants will receive litifilimab during the 28-week extended treatment period from Weeks 24 to 48. More information on the AMETHYST study (NCT05531565) is available at clinicaltrials.gov.

About Litifilimab (BIIB059)
Litifilimab (known as BIIB059), discovered and developed in-house by Biogen scientists, is a humanized IgG1 monoclonal antibody (mAb) targeting BDCA2 and is being investigated for the potential treatment of systemic lupus erythematosus (SLE) and cutaneous lupus erythematosus (CLE). BDCA2 is a receptor that is predominantly expressed on a subset of human immune cells called Plasmacytoid Dendritic Cells (pDCs). Binding of litifilimab to BDCA2 has been shown to reduce production of pro-inflammatory molecules by pDCs, including type-I interferon (IFN-I) as well as other cytokines and chemokines.[1,2] These pro-inflammatory mediators are thought to play a major role in the pathogenesis of systemic and cutaneous lupus.

Litifilimab is an investigational therapeutic candidate that has not yet been approved by any regulatory authority and its safety and effectiveness have not been established.

About Cutaneous Lupus Erythematosus (CLE)
CLE, a type of lupus, is a serious chronic autoimmune skin disease that can occur with or without systemic manifestations; people with CLE frequently experience symptoms including rash, pain, itch and photosensitivity as well as skin damage that may worsen over time and can include irreversible scarring, alopecia and dyspigmentation that can be disfiguring and substantially impact quality of life.[3-6] Currently, there are no approved targeted therapies for CLE and the last drug was approved in the 1950s.

About Biogen

Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patient's 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: the potential clinical effects of litifilimab; the potential of litifilimab to improve the health, wellbeing and outcomes for patients with CLE; the potential benefits, safety and efficacy of litifilimab; potential regulatory discussions, submissions and approvals and the timing thereof; potential therapeutic options for the treatment of CLE; the potential of Biogen's commercial business and pipeline programs, including litifilimab; 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 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:

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6. Drenkard C, Parker S, Aspey LD, Gordon C, Helmick CG, Bao G, Lim SS. Racial Disparities in the Incidence of Primary Chronic Cutaneous Lupus Erythematosus in the Southeastern US: The Georgia Lupus Registry. Arthritis Care Res (Hoboken). 2019 Jan;71(1):95-103. doi: 10.1002/acr.23578. PMID: 29669194; PMCID: PMC6193862.

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