



Biogen's Litifilimab Demonstrates Rapid and Durable Efficacy in New 52-Week Phase 2 Data from Ongoing Phase 2/3 AMETHYST Study, Reinforcing Its Potential as a First-in-Class Therapy for Cutaneous Lupus Erythematosus

October 2, 2026

- **Continued improvement:** An increased response was seen in participants on litifilimab from week 24 through week 52, with more individuals achieving clear or almost clear skin (27.2%; CLA IGA 0-1) and improvements in disease activity (28.8%; CLASI-70) than at week 24 (19.0% and 21.7%, respectively)
- **Rapid onset:** Participants that switched from placebo to litifilimab experienced improvements in skin disease activity in as early as four weeks -- consistent with results seen in participants who started on litifilimab reported earlier this year
- **Consistent safety:** Litifilimab's safety profile remained consistent with previous studies, with no new safety signals identified
- Results from the Phase 3 part of AMETHYST are expected in the first half of 2027; in January 2026 the FDA granted Breakthrough Therapy Designation to litifilimab in CLE

CAMBRIDGE, Mass., Oct. 02, 2026 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BII) today announced 52-week results from the Phase 2 part of the ongoing AMETHYST Phase 2/3 study (Part A) of litifilimab in people living with cutaneous lupus erythematosus (CLE). The updated results, presented at the European Academy of Dermatology and Venereology (EADV) 2026 Congress in Vienna, Austria, represent the longest dataset reported for litifilimab in CLE and further support its potential to achieve rapid and durable improvements in skin disease activity. In the study, participants treated with litifilimab in the double-blind, placebo-controlled period showed continued clinical improvements in skin disease activity through Week 52. Notably, participants who switched from placebo to litifilimab treatment at Week 24 experienced a rapid onset of treatment effect as early as four weeks.

"Access to 52-week data is critical when evaluating a treatment for a lifelong, chronic disease like cutaneous lupus erythematosus, which can cause permanent scarring and disfigurement that many patients will carry with them forever. That is why achieving clear or almost clear skin, which is rarely seen in CLE, is a truly transformative treatment goal for this disease," said Joseph F Merola, MD, MMSc, dermatologist, rheumatologist and President of the Rheumatologic Dermatology Society, Lupus Foundation Medical and Scientific Board. "It is highly encouraging to see continued improvement in skin clearance with litifilimab treatment -- with over a quarter of participants reaching clear or almost clear skin -- and data supporting litifilimab's long-term safety profile."

Litifilimab is being evaluated as a potential once-monthly, first-in-class treatment designed to reduce inflammation at its source by selectively targeting blood dendritic cell antigen 2 (BDCA2) receptors on plasmacytoid dendritic cells (pDCs), which play a central role early in the inflammatory process in CLE. In January 2026, litifilimab was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of CLE.

The Phase 2 portion of the ongoing Phase 2/3 AMETHYST study evaluated 93 adults with active skin symptoms for whom standard antimalarial medications were not effective or not tolerable. Over the course of a full year, the study tracked key measures of skin redness, scaling and disease activity to assess how well litifilimab helped participants achieve healthier skin. By Week 52, more than a quarter (27.2%) of participants who received litifilimab from the beginning of the study achieved the clinical endpoint of clear or almost clear skin, as measured by a Cutaneous Lupus Activity Investigators' Global Assessment Revised (CLA-IGA-R) erythema score of 0 or 1, up from 19.0% at Week 24. Similar improvements were seen on the Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity-70 (CLASI-70) measurement with 28.8% of participants receiving litifilimab from the beginning of the study achieving a 70% or greater reduction in CLASI A at Week 52, compared to 21.7% at Week 24. For participants who started the study on placebo and transitioned to litifilimab halfway through the study, the onset of benefit was rapid -- as early as four weeks -- when skin symptoms began to improve. By Week 52, approximately one in three (33.7%) of these crossover participants reported clear or almost clear skin.

"Living with cutaneous lupus erythematosus carries a heavy physical toll, including dyspigmentation, pain, and scarring, which can be associated with comorbidities like depression and anxiety that can have a profound impact on daily life. These 52-week data reinforce litifilimab's potential to deliver rapid improvement and demonstrate its durable skin clearance effects," said Daniel Quirk, M.D., Chief Medical Officer at Biogen. "We are encouraged by these results that build on findings in earlier studies as we anticipate the upcoming Phase 3 study results that reflect our commitment to advancing targeted therapies for serious autoimmune conditions."

Over the course of the 52-week treatment period, litifilimab was generally well tolerated with a safety profile consistent with previously reported Phase 2 studies and no new safety signals identified. The majority of adverse events (AEs) reported were mild or moderate in severity, and serious AEs occurred in 3.4% (3/88) of participants during the extended treatment period. The most common AEs (≥5% during the extended treatment period) were nasopharyngitis, influenza and arthralgia.

"People living with cutaneous lupus erythematosus face debilitating symptoms, including scarring, hair loss, and extreme sensitivity to light, yet they have long relied on treatments not specifically developed or studied for CLE," said Albert T Roy, President and CEO of the Lupus Research Alliance. "The new data on litifilimab are encouraging because they point to the potential for both rapid symptom relief and durable improvement for people living with this condition. We look forward to seeing additional data from the Phase 3 study."

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 are each 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. The Phase 3 part of the AMETHYST study remains blinded and is expected to read out in the first half of 2027. More information on the AMETHYST

study ([NCT05531565](#)) is available at [clinicaltrials.gov](#).

About Litifilimab (BIIB059)

Litifilimab (known as BIIB059) is an investigational first-in-class monoclonal antibody that is the first potential treatment developed by Biogen for lupus and is being evaluated in patients with systemic lupus erythematosus (SLE) and cutaneous lupus erythematosus (CLE). Its targeted mechanism of action acts early in the disease pathway to address the immune dysregulation that drives lupus. Litifilimab selectively targets BDCA2 receptors on plasmacytoid dendritic cells (pDCs) to reduce inflammation. Biogen developed litifilimab over two decades as part of a dedicated lupus discovery and development program.

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.

Positive results from the CLE portion of the two-part Phase 2 LILAC study were previously published in *The New England Journal of Medicine* (NEJM) [showing](#) litifilimab met the study's primary endpoint by demonstrating superior efficacy to placebo in reducing skin disease activity. In LILAC, litifilimab was generally well tolerated. The AMETHYST ([NCT05531565](#)) Phase 3 trial of litifilimab in CLE is currently ongoing.

About Cutaneous Lupus Erythematosus (CLE)

CLE, a type of lupus, is a serious autoimmune skin disease that impacts the daily lives of patients, including their emotional and mental health. It can lead to disfigurement in the form of hair loss, permanent scarring and abnormal skin color. In CLE, the immune system attacks healthy skin, causing rashes, pain, itching and sensitivity to sunlight. 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 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 relating to, among others, the potential clinical effects of litifilimab; the potential of litifilimab to make a clinically meaningful improvement for patients living with cutaneous lupus erythematosus (CLE); the potential benefits, safety and efficacy of litifilimab; potential regulatory discussions, submissions and approvals and the timing thereof; the expected timing of trial results; the anticipation of Phase 3 trial results; 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, 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.

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