Biogen Highlights Multiple Assets and Indications in Lupus

September 3, 2025

- Lupus is an autoimmune disease with limited treatment options that disproportionally affects women and people who are Black, Asian, Hispanic or Native American
- Biogen has two Phase 3 assets that have demonstrated strong clinical results in both systemic and cutaneous lupus
- Biogen's leading development and commercialization capabilities in autoimmune disease provides a strong foundation to expand into the lupus market

CAMBRIDGE, Mass. – September 3, 2025 – Biogen Inc. (Nasdaq: BIIB) will host a virtual investor seminar today at 10:00 a.m. ET focused on its lupus portfolio led by two potential first-in-class late-stage assets, litifilimab and dapirolizumab pegol (DZP, developed in collaboration with UCB). Lupus is a highly heterogeneous disease, comprising multiple subtypes with symptoms that vary widely by patient. To date, it is estimated that millions of people worldwide have a form of lupus.[1] Building on its deep expertise in pioneering treatments for complex immune conditions like multiple sclerosis (MS), Biogen aims to develop an industry-first lupus portfolio. This includes advancing two Phase 3 assets: litifilimab that has shown strong Phase 2 proof of concept results in systemic lupus erythematosus (SLE) and cutaneous lupus erythematosus (CLE), and dapirolizumab pegol that has completed one positive Phase 3 study in SLE with a second Phase 3 study ongoing.

The webcast will illustrate the science behind the portfolio and strategic opportunities to improve and expand treatment options for people with lupus. Specifically, it will feature the distinct mechanisms of action and compelling data supporting litifilimab and DZP, along with details of the Phase 3 designs and expected timing of data readouts. The company will also highlight its proven capabilities in navigating multifaceted diseases and product launches.

"Lupus is a complex set of diseases with a highly heterogeneous, undertreated patient population that needs more options," said Priya Singhal, M.D., M.P.H., Head of Development at Biogen. "We are advancing multiple therapies with distinct mechanisms of action across lupus indications to address the challenges faced by the lupus community. Strong clinical data from our late-stage programs of litifilimab and dapirolizumab pegol support the potential for a lupus franchise to be a pillar of Biogen's mid to long-term growth."

Join Today's Seminar
To join today's event, please go to the investors section of the Biogen website at investors.biogen.com or access the event link directly. An archived version of the webcast and slides, as well as additional video presentations and slides, will also be available.

Significant Unmet Medical Needs in Lupus

Lupus is a chronic inflammatory disease that occurs when the body's own immune system attacks healthy tissues, including in the skin, joints, kidneys, brain and other organs, causing a wide range of debilitating symptoms and, if not appropriately treated, potentially irreversible damage to the skin and internal organs. There is currently no cure for the estimated 5 million people worldwide[1] who have a form of lupus. Lupus disproportionately affects women of color, particularly Black, Asian, Hispanic and Native American women, who face higher rates of incidence, more severe symptoms, and barriers to care.

Despite the prevalence of lupus, the heterogeneity and involvement of multiple organ systems have been a significant scientific barrier to discovering new, effective treatments. From 1955 through 2011, only one new treatment was approved. Today, there are only two approved treatments for SLE and none for CLE. Additional treatment options are needed as it is estimated that only 20% of people diagnosed with SLE are currently receiving targeted therapies beyond the standard of care.[2]

Systemic Lupus Erythematosus
SLE, the most common form of lupus, is a chronic disease where the immune system attacks the body's own healthy tissues. It can affect multiple organs in the body and often comes in cycles -- with periods of flare-ups followed by times of little or no disease activity. SLE can present itself in different ways, including skin rashes, arthritis, anemia, inflammation around the heart, lungs or abdomen, kidney problems, seizures and changes in mental health.

Cutaneous Lupus Erythematosus

CLE can occur with or without systemic manifestations with frequent symptoms including rash, pain, itch and sensitivity to sunlight as well as skin damage that may worsen over time and can include irreversible scarring, hair loss and abnormal skin color that can be disfiguring and substantially impact quality of life. Presently, there are no treatments approved for CLE.

Litifilimab Clinical Development Program

Litifilimab, discovered and developed in-house by Biogen scientists, is a humanized IgG1 monoclonal antibody (mAb) targeting BDCA2 and is being investigated in patients with SLE and 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. These pro-inflammatory mediators are thought to play a major role in the pathogenesis of systemic and cutaneous lupus.

Positive results from the SLE 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 significantly reducing total number of swollen and tender joints in participants with SLE from baseline compared to placebo over 24 weeks. In LILAC, litifilimab was generally well tolerated. Two Phase 3 trials with litifilimab in SLE, TOPAZ-1 (NCT04895241) and TOPAZ-2 (NCT04961567), are currently ongoing.

The Phase 2 LILAC study with litifilimab was among the first randomized controlled trials in CLE. In 2022, *The New England Journal of Medicine* published positive results from the CLE portion of the LILAC study, which met the primary endpoint with litifilimab demonstrating superior

efficacy to placebo in reducing skin disease activity. In LILAC, litifilimab was generally well tolerated. These positive results supported the initiation of the ongoing pivotal AMETHYST study (NCT05531565) to evaluate the efficacy and safety of litifilimab compared to placebo in CLE.

Dapirolizumab Pegol Clinical Development Program

Dapirolizumab pegol is a novel investigational humanized Fc-free polyethylene glycol (PEG)-conjugated antigen-binding (Fab') fragment. Dapirolizumab pegol inhibits CD40L signaling which has been shown to reduce B cell activation and autoantibody production, mitigate type 1 interferon (IFN) secretion, and attenuate T cell and antigen-presenting cell (APC) activation. Dapirolizumab pegol is presently in Phase 3 clinical development for the treatment of SLE under a collaboration between UCB and Biogen.

In November 2024, Biogen presented, in collaboration with UCB, positive Phase 3 results for DZP, a novel Fc-free anti-CD40L drug candidate and one of only three agents ever to have demonstrated a positive global Phase 3 trial in SLE.

The PHOENYCS GO study (n=321) met its primary endpoint, demonstrating statistically and clinically significant improvement of moderate-to-severe SLE disease activity as measured by the British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA). After 48 weeks, study participants receiving DZP plus standard of care (SOC) had a statistically significant 14.6% (95% confidence interval [CI]: 3.3, 25.8; p=0.0110) higher response rate (49.5%) than those receiving SOC alone (34.6%). In additional analyses of the study, DZP showed efficacy across multiple clinical endpoints, including fatigue and measures of disease activity/remission. Given the key secondary endpoint did not achieve statistical significance, subsequent secondary and tertiary endpoints are descriptive. In the study, the safety profile of DZP was generally favorable.

A second Phase 3 trial of DZP, PHOENYCS FLY (NCT06617325) is in progress and is intended to support a regulatory filing.

The safety and efficacy of dapirolizumab pegol in SLE have not been established, and it is not approved for use in SLE by any regulatory authority worldwide.

In early-stage development, felzartamab is being evaluated in an ongoing Phase 1 study in lupus nephritis.

About Felzartamab

Felzartamab is an investigational therapeutic human monoclonal antibody directed against CD38, a protein expressed on mature plasma cells. Felzartamab is a potential first-in-class therapeutic candidate with promise as a pipeline-in-a-product across a range of immune-mediated diseases. Felzartamab has been shown in clinical studies to selectively deplete CD38+ plasma cells, which may allow applications that ultimately improve clinical outcomes in a broad range of diseases driven by pathogenic antibodies. Felzartamab was originally developed by MorphoSys AG (now MorphoSys GmbH, a Novartis company). Human Immunology Biosciences (HI-Bio) exclusively licensed the rights to develop and commercialize felzartamab across all indications in all countries and territories excluding China (including Macau and Hong Kong and Taiwan). Biogen acquired HI-Bio in July 2024.

Felzartamab 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 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 and the related investor conference call contain forward-looking statements, including relating to: Biogen's aim to develop an industry-first lupus portfolio; the potential benefits, safety and efficacy of litifilimab and dapirolizumab pegol (DZP, developed in collaboration with UCB); the growth potential of lupus treatments given current therapies; the potential for lupus treatments to be a pillar of Biogen's long-term growth; the anticipated benefits, risks and potential of Biogen's collaboration arrangements with UCB; the innovation of our lupus and other pipeline products; Biogen's plan to build on its leading development and commercialization capabilities in autoimmune disease to expand into the lupus market; the potential of Biogen's pipeline in early-stage development, including felzartamab in lupus nephritis; potential regulatory discussions, submissions and approvals and the timing thereof; the risks and uncertainties associated with drug development and commercialization; and our future financial and operating results and financial guidance. 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," and 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 be materially different from those stated or implied in this document, including, among others, factors relating to: 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 presentation and the discussions during this conference call 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 and Form 10-K, in each case including in the sections thereof captioned "Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in our subsequent reports on Form 8-K. 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.

References:

1. Lupus Foundation of America. Lupus Facts and Statistics. 2025. Available at: https://www.lupus.org/resources/lupus-facts-and-statistics. Accessed August 2025.
2. Biogen data on file.

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