Biogen to Present Additional Results from Phase 3 Study of Dapirolizumab Pegol in Systemic Lupus Erythematosus at ACR Convergence 2025

October 22, 2025

- Dapirolizumab pegol (DZP) Phase 3 study presentations in SLE to show efficacy results across multiple clinical endpoints, including low disease activity/remission, flares, fatigue, joint pain and quality of life
- Presentation of preclinical study of DZP showing minimal to no human placental transfer

CAMBRIDGE, Mass., Oct. 22, 2025 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced upcoming presentations from studies evaluating dapirolizumab pegol (DZP), a novel Fc-free anti-CD40L drug candidate, in systemic lupus erythematosus (SLE) to be presented at the American College of Rheumatology (ACR) Convergence 2025 (October 24-29) in Chicago, Illinois. The presentations will show efficacy results of DZP across multiple endpoints including low disease activity/remission, flares, fatigue, joint pain and quality of life. Additional preclinical data will also be presented, demonstrating minimal to no placental transfer of DZP supporting further study in women before, during and after pregnancy.

“The data we are presenting at ACR Convergence strengthen our understanding of the range of effects dapirolizumab pegol has in systemic lupus erythematosus, suggesting it has the potential to broadly impact this chronic and debilitating disease,” said Diana Gallagher, MD, Head of AD, MS and Immunology Development Units at Biogen. “The novel flare analysis of the Phase 3 data presented at ACR, as well as data on quality-of-life metrics and disease activity, further support the potential of dapirolizumab pegol to be a meaningful new therapy in systemic lupus erythematosus. Biogen is committed to advancing its late-stage clinical pipeline which includes programs focusing on the diverse unmet needs of the lupus community.”

Dapirolizumab pegol is one of only three biologics to report positive Phase 3 data in a global SLE study. The additional data presented from the PHOENYCS GO trial at ACR suggest a broad impact across endpoints in this Phase 3 study. In the Phase 3 study, DZP met the primary endpoint of improvement of moderate-to-severe disease activity as assessed by achievement of BICLA after 48 weeks. As the first key secondary endpoint had a p-value = 0.1776, all subsequent secondary and tertiary endpoints are descriptive and nominal p-values are included. A second Phase 3 study, PHOENYCS FLY (NCT06617325), is ongoing.[1,2] Dapirolizumab pegol is being developed under a collaboration between Biogen and UCB.

Details of the presentations are as follows:

- **Title:** Improvement of Fatigue, Musculoskeletal Pain, and Morning Stiffness in Patients with Systemic Lupus Erythematosus Treated with Dapirolizumab Pegol: 48-Week Results from a Phase 3 Trial
  Poster Presentation Date & Time: Sunday, October 26, 2025, Poster Session A, 10:30 AM -12:30 PM CT / 11:30 AM – 1:30 PM ET
  Poster Number: 0644
- **Title:** Achievement of Low Disease Activity and Remission in Patients with Systemic Lupus Erythematosus Treated with Dapirolizumab Pegol: 48-Week Results from a Phase 3 Trial
  Poster Presentation Date & Time: Sunday, October 26, 2025, Poster Session A, 10:30 AM -12:30 PM CT / 11:30 AM – 1:30 PM ET
  Poster Number: 0645
- **Title:** Alternative Definitions of Moderate Flares that Simulate Clinical Practice in Systemic Lupus Erythematosus: Post Hoc Exploration of Moderate Flares in Patients Treated with Dapirolizumab Pegol in a 48-Week Phase 3 Trial
  Poster Presentation Date & Time: Monday, October 27, 2025, Poster Session B, 10:30 AM -12:30 PM CT / 11:30 AM – 1:30 PM ET
  Poster Number: 1542
- **Title:** Dapirolizumab Pegol Demonstrated Improvement in Quality of Life of Patients with Systemic Lupus Erythematosus: LupusQoL Results from a Phase 3 Trial
  Poster Presentation Date & Time: Tuesday, October 28, 2025, Poster Session C, 10:30 AM -12:30 PM CT / 11:30 AM – 1:30 PM ET
  Poster Number: 2441
- **Title:** Dapirolizumab Pegol, a Novel CD40L Inhibitor, Showed No Adverse Outcomes in an In Vivo Non-Human Primate Reprotoxicity Study and Displayed Minimal to No Human Placental Transfer in an Ex Vivo Study
  Abstract Presentation Date & Time: Tuesday, October 28, 2025, Abstract Session, 4:00-4:15 PM CT / 5:00-5:15 PM ET
  Abstract Number: 2631

About Dapirolizumab Pegol
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.[3] Dapirolizumab pegol is presently in Phase 3 clinical development for the treatment of systemic lupus erythematosus (SLE) under a collaboration between UCB and Biogen.[1,2]

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, among others, relating to: the potential benefits, safety and efficacy of dapirolizumab pegol (DZP); the potential of dapirolizumab pegol to be a meaningful new therapy in systemic lupus erythematosus; the anticipated benefits, risks and potential of Biogen's collaboration arrangements with UCB; the potential of Biogen's commercial business and pipeline programs, including dapirolizumab pegol; potential regulatory discussions, submissions and approvals and the timing thereof; and the 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," 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. Clinicaltrials.gov (NCT04294667). A Study to Evaluate the Efficacy and Safety of Dapirolizumab Pegol in Study Participants With Moderately to Severely Active Systemic Lupus Erythematosus (PHOENYCS GO) 2023. Available at: https://clinicaltrials.gov/ct2/show/NCT04294667. Retrieved September 22, 2025.
2. Clinicaltrials.gov (NCT06617325). A Study to Evaluate the Efficacy and Safety of Dapirolizumab Pegol in Study Participants With Moderately to Severely Active Systemic Lupus Erythematosus (PHOENYCS FLY) 2024. Available at https://clinicaltrials.gov/study/NCT06617325. Retrieved September 22, 2025.
3. Furie RA, Bruce IN, Dörner T, et al. Phase 2 randomized, placebo-controlled trial of dapirolizumab pegol in patients with moderate to severe active systemic lupus erythematosus (SLE). Rheumatology (Oxford).2021;60(11): 5397-407.

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