# Dapirolizumab Pegol Phase 3 Data in SLE Presented at the Annual European Congress of Rheumatology (EULAR) Show Improvement in Fatigue and Reduction in Disease Activity

June 12, 2025

- Dapirolizumab pegol (DZP) showed efficacy across multiple clinical endpoints in the PHOENYCS GO study, including fatigue and measures of disease activity
- DZP showed consistent improvements in fatigue, a common and debilitating symptom of systemic lupus erythematosus (SLE)
- At Week 48, more individuals receiving DZP experienced no or low disease activity compared to standard of care with differences observed as early as Week 12

BRUSSELS and CAMBRIDGE, Mass., June 12, 2025 (GLOBE NEWSWIRE) -- UCB (Euronext Brussels: UCB) and Biogen Inc. (NASDAQ: BIIB) today presented additional detailed results from the Phase 3 PHOENYCS GO study evaluating dapirolizumab pegol (DZP), a novel Fc-free anti-CD40L drug candidate. In the study, DZP demonstrated significant clinical improvements in disease activity in people living with moderate-to-severe systemic lupus erythematosus (SLE), as measured by the British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA) at Week 48, the primary endpoint. Improvements were also seen across additional clinical measures, including fatigue and disease activity/remission. These results were presented at EULAR 2025, the European Alliance of Associations for Rheumatology's annual meeting, in Barcelona, Spain. The safety and efficacy of DZP in SLE have not been established, and it is not approved for use in SLE by any regulatory authority worldwide. A second Phase 3 trial of dapirolizumab pegol is ongoing with the goal of confirming the results from PHOENYCS GO.

"Despite being a common manifestation of systemic lupus erythematosus, fatigue is a difficult-to-treat symptom that can severely impact a person's quality of life, and remains a challenge to address," said Ioannis Parodis, MD, PhD, Associate Professor of Rheumatology, Karolinska University Hospital, Sweden. "The results we observed in this Phase 3 study indicate that participants treated with dapirolizumab pegol have the potential to achieve consistent improvements in fatigue beyond the current standard of care."

In an analysis of the impact of DZP on patient-reported fatigue in people with SLE participating in the PHOENYCS GO study, individuals receiving DZP in addition to standard of care (SOC) treatment demonstrated improvements across two fatigue measurements:

- Improvements in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue scores were greater in the DZP group (change from baseline, 8.9), compared with SOC alone (5.2; nominal* p=0.0024) at Week 48.
- Using FATIGUE-PRO, a measure recently developed to capture the patient experience of fatigue in SLE, greater improvements from baseline (nominal* p<0.05) were observed in people receiving DZP compared with SOC alone in the Physical Fatigue (change from baseline difference between groups,7.6), Mental and Cognitive (5.6), and Susceptibility to Fatigue (7.8) scales at Week 48.

"Being able to address both fatigue and remission are areas of critical unmet need in lupus care, an important treatment goal is to improve the quality of life for patients as well as to reduce the long-term risk of organ damage through disease remission," said Eric F. Morand, MBBS, Head of the Monash Health Rheumatology Unit, Monash University, Australia. "In the PHOENYCS GO study, dapirolizumab pegol has shown meaningful impact in helping patients achieve remission and low disease activity, offering the exciting possibility for improved disease control while reducing exposure to glucocorticoids. Dapirolizumab pegol has the potential to become a significant new medication for people living with SLE, as shown by the breadth of effect seen in the study and I look forward to seeing results from the second Phase 3 study."

In an additional analysis, improvements were seen on measures of low disease activity, as measured by Low Lupus Disease Activity State (LLDAS) and disease remission, as measured by Definition of Remission in SLE (DORIS). Both measures include assessments of disease activity, in addition to a required low dose glucocorticoid intake (<7.5 mg prednisone / day in LLDAS; <5 mg prednisone / day in DORIS).

- At Week 48, the percentage of participants achieving low disease activity in the DZP group was twice that of the SOC only group (40.9% and 19.6%, respectively; nominal* p<0.0001). As early as Week 12, greater proportions of participants receiving DZP plus SOC achieved LLDAS versus SOC alone (nominal* p<0.05).
- 23.6% of participants receiving DZP plus SOC achieved low disease activity in ≥50% of visits through 48 weeks compared with 15.9% receiving SOC alone (nominal* p=0.1042).
- A higher proportion of those receiving DZP (19.2%) versus SOC alone (8.4%) also achieved DORIS at Week 48 (nominal* p=0.0056).

* Having met the primary endpoint, improvement of moderate-to-severe disease activity as assessed by achievement of BICLA after 48 weeks and the key secondary endpoint having a p-value = 0.1776, all subsequent secondary and tertiary endpoints are descriptive and nominal p-values are included.

The safety profile of DZP was generally favorable. The safety results were consistent with previous DZP studies and with that in study participants with SLE receiving an immunomodulator. A higher proportion of individuals receiving DZP plus SOC had treatment-emergent adverse events (TEAEs) compared to SOC alone (82.6% vs. 75.0%). The proportion of participants with serious TEAEs was 9.9% in participants receiving DZP plus SOC was lower as compared to 14.8% in those receiving SOC alone. Discontinuation of treatment or study participation due to TEAEs occurred in 4.7% (10) of participants receiving DZP plus SOC and 3.7% (4) of participants receiving SOC alone.

Participants from the PHOENYCS GO study (NCT04294667) will continue to be followed in a long-term open-label study. A second Phase 3 trial of dapirolizumab pegol, PHOENYCS FLY (NCT06617325) is ongoing.

**About Systemic Lupus Erythematosus (SLE)**
SLE is a chronic, multifactorial autoimmune disease that is caused by the activation of autoreactive T, B and antigen-presenting cells, resulting in manifestations across multiple organ systems with periods of illness or flares alternating with periods of inactivity.[1] SLE can present itself in several ways including rash, arthritis, anemia, thrombocytopenia, serositis, nephritis, seizures or psychosis.[2] SLE is associated with a greater risk of death from causes such as infection and cardiovascular disease.

An estimated 90% of people living with lupus are women; most begin to see symptoms between the ages of 15-55.[3,4,5] Individuals from populations of African, Hispanic, Asian and Native American descent are at a greater risk of earlier onset and more aggressive disease.[6,7] Pregnancy in women with SLE is high risk, with higher maternal and fetal mortality and morbidity than the general population.[8,9]

**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.[10] Dapirolizumab pegol is presently in Phase 3 clinical development for the treatment of systemic lupus erythematosus (SLE) under a collaboration between UCB and Biogen.[11]

**About UCB**
UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With approximately 9,000 people in approximately 40 countries, the company generated revenue of €6.1 billion in 2024. UCB is listed on Euronext Brussels (symbol: UCB).

**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.

The company routinely posts information that may be important to investors on its website at www.biogen.com. Follow us on social media - Facebook, LinkedIn, X, YouTube.

**Forward looking statements UCB**
This document contains forward-looking statements, including, without limitation, statements containing the words "potential", "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guaranteeing future performance and are subject to known and unknown risks, uncertainties, and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document. Important factors that could result in such differences include but are not limited to: global spread and impacts of wars, pandemics and terrorism, the general geopolitical environment, climate change, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues, supply chain disruption and business continuity risks; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars or disruptive technologies/business models, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring, retention and compliance of its employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB's efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, the public is cautioned not to place any undue reliance on such forward-looking statements. These forward-looking statements are made only as of the date of this document, and do not reflect any potential impacts from the evolving event or risk as mentioned above as well as any other adversity, unless indicated otherwise. The company continues to follow the development diligently to assess the financial significance of these events, as the case may be, to UCB.

UCB expressly disclaims any obligation to update any forward-looking statements in this document, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

**Biogen Safe Harbor**
This press release contains forward-looking statements, relating to: our strategy and plans; potential of, and expectations for, our commercial business and pipeline programs; capital allocation and investment strategy; clinical development programs, clinical trials, and data readouts and presentations; regulatory discussions, submissions, filings, and approvals; the potential benefits, safety, and efficacy of our and our collaboration partners' products

and investigational therapies; the anticipated benefits and potential of investments, actions to improve risk profile and productivity of R&D pipeline, collaborations, and business development activities; and our future financial and operating results. 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. This press release includes, among others, forward-looking statements including: that Biogen is building on a new foundation with the goal of long-term sustainable growth in its commercial portfolio; the multi-billion dollar potential of its late-stage pipeline; that we believe there remains a significant long-term opportunity for our ongoing product launches including LEQEMBI; that we believe that continued execution against these key strategic elements, as well as a disciplined approach to business development, will allow us to generate long-term value for our shareholders by bringing innovative medicines to patients; and all statements and information under the heading "Full Year 2025 Financial Guidance". 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: our substantial dependence on revenue from our products and other payments under licensing, collaboration, acquisition or divestiture agreements; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; expectations, plans and prospects 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; the successful execution of our strategic and growth initiatives, including acquisitions; the drivers for growing our business; 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 associated with current and potential future healthcare reforms; 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; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; 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; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to technology, including our incorporation of new technologies such as artificial intelligence into some of our processes; risks related to use of information technology systems and potential impacts of any breakdowns, interruptions, invasions, corruptions, data breaches, destructions and/or other cybersecurity incidents of our systems or those of connected and/or third-party systems; problems with our manufacturing capacity, including our ability to manufacture products efficiently or adequately address global bulk supply risks; risks relating to management, personnel and other organizational changes, including our ability to attracting, retaining and motivating qualified individuals; risks related to the failure to comply with current and new legal and regulatory requirements, including judicial decisions, accounting standards, and tariff or trade restrictions; the risks of doing business internationally, including geopolitical tensions, acts of war and largescale crises; risks relating to investment in our manufacturing capacity; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business, results of operations and financial condition; fluctuations in our operating results; risks related to investment in properties; risks relating to access to capital and credit markets to finance our present and future operations and business initiatives and obtain funding for such activities on favorable terms; risks related to indebtedness; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate and obligations in various jurisdictions in which we are subject to taxation; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

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 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. Tselios K, Gladman DD, Touma Z, et al. Disease course patterns in systemic lupus erythematosus. Lupus. 2019;28(1):114-122.

2. Fanouriakis A, Tziolos N, Bertsias G, et al. Update on the diagnosis and management of systemic lupus erythematosus. Ann Rheum Dis. 2021;80(1):14-25. doi:10.1136/annrheumdis-2020-218272

3. Petri M. Epidemiology of systemic lupus erythematosus. Best Pract Res Clin Rheumatol. 2002;16(5):847-58. Epub 2002/12/11. doi: 10.1053/berh.2002.0259. PubMed PMID: 12473278.

4. Rees F, Doherty M, Grainge M, Davenport G, Lanyon P, Zhang W. The incidence and prevalence of systemic lupus erythematosus in the UK, 1999-2012. Ann Rheum Dis. 2016;75(1):136-41. Epub 2014/10/01. doi: 10.1136/annrheumdis-2014-206334. PubMed PMID: 25265938; PubMed Central PMCID: PMCPMC4717400.

5. Pons-Estel GJ, Ugarte-Gil MF, Alarcón GS. Epidemiology of systemic lupus erythematosus. Expert Rev Clin Immunol. 2017;13(8):799-814.

6. Carter EE, Barr SG, Clarke AE. The global burden of SLE: prevalence, health disparities and socioeconomic impact. Nat Rev Rheumatol. 2016;12(10):605-20. Epub 2016/08/26. doi: 10.1038/nrrheum.2016.137. PubMed PMID: 27558659.

7. Kheir JM, Guthridge CJ, Johnston JR, Adams LJ, Rasmussen A, Gross TF, et al. Unique clinical characteristics, autoantibodies and medication use in Native American patients with systemic lupus erythematosus. Lupus Sci Med. 2018;5(1):e000247. Epub 2018/03/14. doi: 10.1136/lupus-2017-000247. PubMed PMID: 29531773; PubMed Central PMCID: PMCPMC5844376.

8. Mehta B, Luo Y, Xu J, Sammaritano L, Salmon J, Lockshin M, et al. Trends in Maternal and Fetal Outcomes Among Pregnant Women With Systemic Lupus Erythematosus in the United States: A Cross-sectional Analysis. Ann Intern Med. 2019;171(3):164-71. Epub 2019/07/10. doi: 10.7326/M19-0120. PubMed PMID: 31284305.

9. Bitencourt N, Bermas BL. Pharmacological Approach to Managing Childhood-Onset Systemic Lupus Erythematosus During Conception, Pregnancy and Breastfeeding. Paediatr Drugs.

10. 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.

11. 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 [cited August 2024] Available at: https://clinicaltrials.gov/ct2/show/NCT04294667. Retrieved July 25, 2024.

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