UCB and Biogen Announce Publication in The Lancet of Positive Dapirolizumab Pegol (DZP) Phase 3 Study Results in Systemic Lupus Erythematosus

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- Publication adds to previously reported findings from Phase 3 PHOENYCS GO study, demonstrating statistically significant improvement in disease activity at Week 48 with dapirolizumab pegol plus standard of care versus placebo plus standard of care
- Findings showed results in favor of dapirolizumab pegol plus standard of care versus placebo plus standard of care across endpoints, including multiple disease activity measures, severe flares, patient-reported outcomes, including fatigue, and glucocorticoid tapering
- Results support the continued development of dapirolizumab pegol; the ongoing confirmatory Phase 3 PHOENYCS FLY clinical trial is currently recruiting

BRUSSELS, Belgium and CAMBRIDGE, Mass., June 01, 2026 (GLOBE NEWSWIRE) -- UCB (Euronext Brussels: UCB) and Biogen Inc. (Nasdaq: BIIB) today announced that *The Lancet,* a world-leading medical journal, has published the full results from the Phase 3 PHOENYCS GO clinical trial evaluating dapirolizumab pegol (DZP), an investigational, novel Fc-free CD40L inhibitor, in patients living with moderate-to-severe active systemic lupus erythematosus (SLE). The results showed statistically significant improvement in disease activity with DZP added to standard of care (SOC) versus placebo plus standard of care.[1]

"The publication of the PHOENYCS GO results in *The Lancet* reflects the importance of these data to the rheumatology community, providing evidence of dapirolizumab pegol as a potential treatment option for people living with systemic lupus erythematosus," said Megan E. B. Clowse, M.D., MPH, Chief of the Division of Rheumatology and Immunology, Duke University, and primary author of the publication. "Given the acute need for additional treatment options for SLE, these findings are encouraging for both clinicians and patients and clearly warrant further evaluation in the confirmatory Phase 3 PHOENYCS FLY study."

In the Phase 3 study, DZP successfully met the primary endpoint: a significantly greater proportion of patients receiving DZP plus standard of care (SOC) achieved British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA) response at Week 48 (50%; 103/208) compared to placebo plus SOC (35%; 37/107; p=0.011).[1] BICLA is a composite endpoint measuring clinically relevant improvement of disease activity across all affected organ systems with no worsening in other lupus domains; a higher BICLA response rate reflects a treatment response and is associated with clinical benefit.[1]

Because the first key secondary endpoint was not met (BICLA response at week 24), subsequent outcomes were not controlled for multiplicity. Results in favor of DZP plus SOC were observed across multiple outcomes, including severe BILAG flares, SRI-4, SLEDAI-2K, skin- and joint-related outcomes, and the serological markers anti-dsDNA antibodies and complement C3 and C4.[1] Additionally, at week 48 the data showed clinically meaningful improvements in patient-reported FACIT-Fatigue, which is often cited by patients as one of the most debilitating symptoms of SLE.[1,2] Importantly, these results were achieved within the context of glucocorticoid tapering in line with treatment guidelines.[1,3] At week 48, a greater proportion of patients in the DZP plus SOC group versus PBO plus SOC were able to reduce their glucocorticoid dose from >7.5 mg/day to ≤7.5 mg/day, suggesting a glucocorticoid-sparing effect of DZP.[1]

In the PHOENYCS GO study, DZP demonstrated a generally favorable safety profile, with safety findings consistent with previous DZP studies.[1,4] Treatment-emergent adverse events (TEAEs) were more common with DZP plus SOC versus PBO plus SOC (82.6% [176/213] vs. 75.0% [81/108], respectively), while serious TEAEs were less frequent in the DZP plus SOC arm (10.0% [21/213] vs. 14.8% [16/108]) respectively.[1] Discontinuations due to TEAEs were low in both groups (4.7% vs. 3.7%) respectively.[1]

These positive Phase 3 results support the continued development of DZP. UCB and Biogen are actively progressing the confirmatory Phase 3 PHOENYCS FLY clinical trial (NCT06617325), which is currently recruiting patients and is intended to support future regulatory filings.[5]

Further data from the PHOENYCS GO study will be presented this week at the Annual European Congress of Rheumatology (EULAR).

About Dapirolizumab Pegol

Dapirolizumab pegol is a novel investigational humanized Fc-free polyethylene glycol (PEG)-conjugated antigen-binding (Fab') fragment. [4] 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.[4] Dapirolizumab pegol is presently in Phase 3 clinical development for the treatment of systemic lupus erythematosus (SLE) under a collaboration between UCB and Biogen.[5,6]

Dapirolizumab pegol is an investigational biologic currently in clinical development. The safety and efficacy have not been established, and it is not approved by any health authority worldwide.

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 11,000 people in approximately 40 countries, the company generated revenue of €7.7 billion in 2025. 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.

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.

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 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 an important option in addressing the effects of 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, 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.

Biogen 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 these social media channels in addition to our press releases, SEC filings, public conference calls and websites, as the information posted on them could be material to investors.

References:

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5. 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 May 18, 2026.

6. 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 May 18, 2026.

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