ACR 2026: Dapirolizumab Pegol Associated with Greater Treatment Response Rates Versus Placebo in SLE Using Novel Treatment Response Measure

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- **Dapirolizumab pegol (DZP) associated with higher response rates using the novel Treatment Response Measure for Systemic Lupus Erythematosus (TRM-SLE):** A post-hoc analysis applying TRM-SLE to the DZP Phase 3 PHOENYCS GO data for the first time found greater proportions of patients receiving DZP plus standard of care (SOC) versus placebo plus SOC achieved a clinically meaningful response in at least half or all active organ domains through Week 48
- **Sustained low disease activity and remission:** In a separate presentation at ACR 2026, post-hoc analyses of PHOENYCS GO showed greater rates of sustained low disease activity and remission across Weeks 40, 44 and 48 with DZP plus SOC versus placebo plus SOC

BRUSSELS and CAMBRIDGE, Mass., Nov. 09, 2026 (GLOBE NEWSWIRE) -- UCB (Euronext Brussels: UCB) and Biogen Inc. (Nasdaq: BIIB) today announced further data characterizing the clinical profile of dapirolizumab pegol (DZP), an investigational biologic for people living with systemic lupus erythematosus (SLE). The data are being presented across five posters at ACR Convergence 2026, the annual meeting of the American College of Rheumatology, in Orlando, Florida, November 6-11.

In a post-hoc analysis of the DZP Phase 3 PHOENYCS GO study using the Treatment Response Measure for Systemic Lupus Erythematosus (TRM-SLE), a novel clinical outcome assessment, DZP plus standard of care (SOC) was associated with greater proportions of patients achieving a clinically meaningful response through Week 48 in at least half (TRM-SLE-50) or all (TRM-SLE-100) of their active organ domains, mainly joints and skin, versus placebo plus SOC (Poster 1296).[1]

“In SLE, patients can improve in ways that matter to them, such as less joint pain or clearer skin, yet fail to register as a treatment responder based on today's trial measures,” said Professor Eric F. Morand, Centre for Inflammatory Diseases, Monash University, Melbourne, Australia, and co-author of the analysis. “TRM-SLE is designed to provide a simple, patient-centric and clinically intuitive assessment. Applying it to Phase 3 data for the first time is an important step toward a potential future primary outcome measure for clinical studies, one that mirrors how both patients and clinicians judge response.”

Difficulty measuring clinically meaningful response to treatment has hindered progress in clinical trials for SLE and impeded the approval of potential new therapies.[2] To address this, a global taskforce led by Monash University, with clinicians, patient representatives, industry partners and regulatory experts, developed the TRM-SLE as a novel clinical outcome assessment that measures clinically meaningful treatment effects across select organ domains in SLE trials.[2,3]

In PHOENYCS GO, DZP plus SOC met the primary endpoint of BICLA response at Week 48 versus placebo plus SOC, with results also favoring DZP for SRI-4 response (60% [125/208] vs 41% [44/107]), a secondary outcome not controlled for multiplicity.[4] In the TRM-SLE analysis, DZP plus SOC through Week 48 was associated with a greater proportion of patients achieving TRM-SLE-50 (61.2% vs 43.2%) and TRM-SLE-100 (52.5% vs 36.8%) compared with placebo plus SOC, representing clinically meaningful improvements in at least half or all of their active organ domains, respectively. At baseline, patients primarily fulfilled the arthritis (joint) and mucocutaneous (skin) TRM-SLE domains.[1]

The authors concluded that TRM-SLE distinguished response rates between the treatment arms and offers a potentially practical way to determine response to therapy in patients with SLE, while noting that further validation of the measure is needed.[1] TRM-SLE was applied here as a post-hoc analysis rather than as a pre-specified endpoint or as part of any regulatory submission.

“Progress in SLE depends not only on new medicines, but on how we recognize and measure meaningful outcomes,” said Donatello Crocetta, Chief Medical Officer and Head of Global Medical Affairs at UCB. “UCB and Biogen are pleased to support the taskforce behind TRM-SLE, and applying this framework to our Phase 3 data, alongside our analyses of sustained low disease activity and remission, reflects our commitment to advancing the science of meaningful and sustained treatment outcomes in SLE. By helping refine how treatment response is evaluated, we hope to support better evidence generation, contribute to evolving standards in SLE trials and, ultimately, better outcomes for people living with this condition.”

Sustaining Low Disease Activity and Remission in Patients with SLE
In a separate presentation, post-hoc analyses of PHOENYCS GO examined sustained attainment of low disease activity and remission with DZP plus SOC, endpoints of recognized prognostic importance in SLE. Across the final three study visits (Weeks 40, 44 and 48), greater proportions of patients receiving DZP plus SOC versus placebo plus SOC were found to achieve sustained LLDAS (24.0% [50/208] vs 10.3% [11/107]; nominal p=0.0012), sustained LLDAS-5, which requires a glucocorticoid dose of ≤5 mg/day prednisone equivalent (19.2% [40/208] vs 5.6% [6/107]; nominal p=0.0002), and sustained DORIS (11.5% [24/208] vs 4.7% [5/107]; nominal p=0.0253) (Poster 2196).[5]

“Our understanding of SLE has evolved, and so must the way we research potential treatments. Following the science means using additional measurement tools to fully understand how our treatments could potentially benefit people living with SLE. We are excited that this first application of TRM-SLE to Phase 3 trial data adds to the evidence reflecting the potential of dapirolizumab pegol. We are committed to deepening our understanding of the disease, advancing the science and ultimately helping improve outcomes for people living with SLE,” said Diana Gallagher, MD, Head of the Immune-Mediated and Neurodegeneration Development Unit at Biogen.

The Phase 3 PHOENYCS GO study was published in *The Lancet* in May 2026, reporting statistically significant and clinically meaningful improvement in disease activity with DZP plus SOC versus placebo plus SOC at Week 48, as measured by BICLA response (50% [103/208] vs 35% [37/107]; p=0.011).[4] In the study, DZP showed a generally favorable safety profile, with safety findings consistent with previous DZP studies.[4,6] Treatment-emergent adverse events were more common with DZP plus SOC versus placebo plus SOC, while serious treatment-emergent adverse events were

less frequent in the DZP plus SOC arm, and discontinuations due to treatment-emergent adverse events were low in both groups.[4]

Additional Information

- **TRM-SLE:** Treatment Response Measure for Systemic Lupus Erythematosus (TRM-SLE), a novel clinical outcome assessment developed by a global taskforce with regulatory input. It assesses response in each patient's active organ domains, drawn from six: arthritis, mucocutaneous, nephropathy, serositis, hemolytic anemia and thrombocytopenia.[1,3]
- **TRM-SLE-50/100:** clinically meaningful improvement in at least half (TRM-SLE-50) or all (TRM-SLE-100) of a patient's active TRM-SLE domains.[1]
- **BICLA:** British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA), the primary endpoint of PHOENYCS GO. A BICLA response requires improvement in all organ systems active at baseline without worsening in others, no worsening in Systemic Lupus Erythematosus Disease Activity Index-2000 (SLEDAI-2K) total score, and no significant deterioration in Physician Global Assessment (PGA).[4]
- **SRI-4:** SLE Responder Index-4 (SRI-4), a composite measure based primarily on improvement in SLEDAI-2K score.[4]
- **LLDAS / LLDAS-5:** Lupus Low Disease Activity State (LLDAS). LLDAS-5 is LLDAS with a glucocorticoid dose of ≤5 mg/day prednisone equivalent.[5]
- **DORIS:** Definitions of Remission in SLE (DORIS).[5]
- **Sustained LLDAS, LLDAS-5 and DORIS:** achieved at each of the final three study visits (Weeks 40, 44 and 48).[5]

About Dapirolizumab Pegol

Dapirolizumab pegol is a novel investigational humanized Fc-free polyethylene glycol (PEG)-conjugated antigen-binding (Fab') fragment. [6] 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.[6] Dapirolizumab pegol is presently in Phase 3 clinical development for the treatment of systemic lupus erythematosus (SLE) under a collaboration between UCB and Biogen.[7,8]

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 is a global biopharmaceutical company inspired by the needs of people living with severe diseases and driven by science to make a meaningful difference in their lives. We combine our understanding of disease biology, scientific innovation and patient insights to develop differentiated medicines and solutions, with a focus on neurology, immunology and other areas of unmet medical need. Founded in Belgium in 1928, UCB has more than 10,000 employees in approximately 40 countries and 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 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.

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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 UCB's 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 laws and/or rules pertaining to tax and duties or the administration of such laws and/or rules, and hiring, retention and compliance of 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 address the needs of people living with systemic lupus erythematosus (SLE); 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.

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