UCB and Biogen Announce Positive Topline Results From Phase 3 Study of Dapirolizumab Pegol in Systemic Lupus Erythematosus and are Initiating Second Phase 3 Study in 2024

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- Phase 3 PHOENYCS GO study met the primary endpoint demonstrating clinical improvement in moderate-to-severe systemic lupus erythematosus; Clinical improvements were observed among key secondary endpoints measuring disease activity and flares.
- UCB and Biogen are advancing dapirolizumab pegol with the objective to address the substantial unmet medical need for people living with SLE, where there are limited treatment options.
- SLE is a chronic, debilitating autoimmune disease that affects multiple organ systems and disproportionately affects women.

BRUSSELS and CAMBRIDGE, Mass., Sept. 24, 2024 (GLOBE NEWSWIRE) -- UCB (Euronext Brussels: UCB) and Biogen Inc. (NASDAQ: BIIB) today announced positive topline results from the Phase 3 PHOENYCS GO study evaluating dapirolizumab pegol, a novel Fc-free anti-CD40L drug candidate, in people living with moderate-to-severe systemic lupus erythematosus (SLE). Dapirolizumab pegol, in addition to standard-of-care (SOC) treatment, met the primary endpoint to demonstrate greater improvement of moderate-to-severe disease activity as assessed by achievement of British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA) after 48 weeks versus placebo in addition to SOC. Clinical improvements were observed among key secondary endpoints measuring disease activity and flares.

The safety profile of dapirolizumab pegol was generally consistent with previous studies and with that expected in study participants with systemic lupus erythematosus receiving an immunomodulator.

“These positive results with dapirolizumab pegol represent encouraging progress in the development of medicines that can improve the lives of those living with lupus, an area that remains one of high unmet medical need and where women are disproportionately affected,” said Fiona du Monceau, Head of Patient Evidence at UCB. "We have confidence in the unique mode of action of dapirolizumab pegol which targets multiple inflammatory pathways involved in the pathogenesis of SLE. As we pursue the next steps in the clinical development of this potentially differentiated treatment, we extend our appreciation to the patients, study investigators and the clinical community for their ongoing support and participation in this important research.”

Based on the successful outcome of the PHOENYCS GO study, UCB and Biogen are initiating a second Phase 3 trial of dapirolizumab pegol in 2024, PHOENYCS FLY. Participants from the PHOENYCS GO study will continue to be followed in a long-term open-label study.

“Our hypothesis is that impacting the CD40L pathway, a central mechanism in immune response, would translate to significant impact on SLE disease burden. These results demonstrate that dapirolizumab pegol has the promise to provide meaningful benefit in this serious, chronic, and often devastating disease,” said Diana Gallagher, MD, Head of AD, MS and Immunology Development Units at Biogen. “We are committed to delivering new treatment options for this autoimmune disease and believe the overall efficacy and safety seen in PHOENYCS GO support further development of dapirolizumab pegol in SLE.”

PHOENYCS GO (n= 321) is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study of dapirolizumab pegol as an add on therapy to standard of care compared to placebo with standard of care. The primary outcome measure was improvement of moderate-to-severe disease activity at Week 48 using BICLA, an established, composite primary efficacy endpoint for measurement of clinical disease activity based on patient medical history, clinical examination and laboratory tests.

Detailed results from the PHOENYCS GO study will be presented at an upcoming medical congress.

About Systemic Lupus Erythematosus (SLE)
SLE, the systemic form of lupus, is a chronic, multifactorial autoimmune disease that can affect 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 percent 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 (http://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. 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 post information that may be important to investors on its website at www.biogen.com. Follow us on social media - Facebook, LinkedIn, X, YouTube.

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Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

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This news release contains forward-looking statements, including but not limited to those relating to the potential benefits, safety and efficacy of DZP; the timing and status of current and future regulatory filings; risks and uncertainties associated with drug development and commercialization; the potential of Biogen's commercial business and pipeline programs; the anticipated benefits and potential of Biogen's collaboration arrangements with UCB; Biogen's strategy and plans; and potential cost healthcare savings related to biosimilars. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "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 or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation, actual timing and content of submissions to and decisions made by the regulatory authorities regarding DZP; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of DZP; risks of unexpected costs or delays or other unexpected hurdles; uncertainty of success in the development and potential commercialization of DZP, which may be impacted by, among other things, the level of preparedness of healthcare providers to treat patients, difficulties in obtaining or changes in the availability of reimbursement for DZP and other unexpected difficulties or hurdles; the occurrence of adverse safety events; unexpected concerns that may arise from additional data or analysis; failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; risks of legal actions, regulatory scrutiny or other challenges to biosimilars, results of operations and financial condition; product liability claims; and third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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