UCB and Biogen Announce Topline Results from a Phase 2b Study of Dapirolizumab Pegol in Systemic Lupus Erythematosus

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BRUSSELS, Belgium and CAMBRIDGE, Mass., Oct. 23, 2018 (GLOBE NEWSWIRE) -- Today UCB (Euronext Brussels: UCB) and Biogen Inc. (Nasdaq: BIIB) announced top-line results from a Phase 2b study evaluating the safety and efficacy of dapirolizumab pegol (DZP), an anti-CD40L pegylated Fab, in adults with moderately-to-severely active systemic lupus erythematosus (SLE) despite receiving standard-of-care treatment such as corticosteroids, anti-malarials and non-biological immunosuppressants.

The primary endpoint of the study to demonstrate a dose response at 24 weeks on the British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA) was not met (p=0.06). The study did demonstrate consistent and potentially meaningful improvements for the majority of clinical endpoints in patients treated with DZP compared with placebo. In addition, biomarker data demonstrated evidence of proof of biology. DZP was well tolerated and demonstrated an acceptable safety profile.

Biogen and UCB continue to further evaluate these data while assessing potential next steps. The companies expect to present this data at a future scientific forum.

About Dapirolizumab Pegol
Dapirolizumab pegol is an investigational anti-CD40L pegylated Fab being developed in systemic lupus erythematosus (SLE) jointly by UCB and Biogen. Through interactions with its receptor, CD40, CD40L plays an important role in regulating interactions between T cells and other immune cells, notably B cells and antigen presenting cells, and thus affects several important functional events thought to be involved in autoimmune disease.

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 more than 7 500 people in approximately 40 countries, the company generated revenue of € 4.5 billion in 2017. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

About Biogen
At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp, and today has the leading portfolio of medicines to treat multiple sclerosis; has introduced the first and only approved treatment for spinal muscular atrophy; and is focused on advancing neuroscience research programs in Alzheimer's disease and dementia, multiple sclerosis and neuroimmunology, movement disorders, neuromuscular disorders, pain, ophthalmology, neuropsychiatry, and acute neurology. Biogen also manufactures and commercializes biosimilars of advanced biologics.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Forward looking statements UCB
This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, 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, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction. UCB is providing this information as of the date of this document and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to potential clinical effects of dapirolizumab pegol; the potential benefits, safety and efficacy of dapirolizumab pegol; risks and uncertainties associated with drug development and commercialization; the results of certain real-world data; the timing and scope of future clinical trials, if any, including for dapirolizumab pegol; and the potential of Biogen's commercial business and pipeline programs, including dapirolizumab pegol. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate,"

“except,” “forecast,” “goal,” “intend,” “may,” “plan,” “potential,” “possible,” “will” 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 unexpected concerns that may arise from additional data, analysis or results obtained during clinical trials; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen’s drug candidates, including dapirolizumab pegol; risks of unexpected costs or delays; uncertainty of success in the development and potential commercialization of dapirolizumab pegol, which may be impacted by, among other things, failure to protect and enforce Biogen’s data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; Biogen may encounter other unexpected hurdles which may be impacted by, among other things, the occurrence of adverse safety events or failure to obtain regulatory approvals in certain jurisdictions; product liability claims; or 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 Securities and Exchange Commission. These statements are based on Biogen’s current beliefs and expectations and speak only as of the date of this press 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.

For further information:

UCB Corporate Communications
France Nivelle,
Global Communications, UCB
T +32.2.559.9178,
france.nivelle@ucb.com

Laurent Schots
Global Communications, UCB
T +32.2.559.92.64
laurent.schots@ucb.com

UCB Investor Relations
Antje Witte,
Investor Relations, UCB
T +32.2.559.94.14,
antje.witte@ucb.com

Neil Wallace,
Investor Relations, UCB
T +32.2.386.2869,
neil.wallace@ucb.com

Biogen Media Contact
David Caouette
+1 617 679 4945
public.affairs@biogen.com

Biogen Investor Relations Contact
Matt Calistri
+1 781 464 2442
IR@biogen.com