Biogen Presents Positive Phase 2 Cutaneous Lupus Erythematosus (CLE) Data at European E-Congress of Rheumatology (EULAR) 2020

June 4, 2020

- Full analysis of the CLE part of the LILAC study reinforces positive top-line results; participants who received BIIB059 (anti-BDCA2) demonstrated statistically significant reduction of disease activity compared to those who received placebo
- Safety and tolerability data further support the continued development of BIIB059
- Results underscore Biogen's efforts to develop and deliver novel disease-modifying therapeutic options for people impacted by lupus, a chronic autoimmune disease characterized by skin lesions and/or systemic manifestations

CAMBRIDGE, Mass., June 04, 2020 (GLOBE NEWSWIRE) -- Today, Biogen Inc. (Nasdaq: BIIB) shared positive data from the 16-week cutaneous lupus erythematosus (CLE) portion of the Phase 2 LILAC study. The study evaluated the efficacy and safety of BIIB059, a fully humanized IgG1 monoclonal antibody (mAb) targeting blood dendritic cell antigen 2 (BDCA2) expressed on plasmacytoid dendritic cells (pDCs). The data were presented at the European E-Congress of Rheumatology (EULAR) 2020, being held virtually from June 3-6, 2020.

"We are encouraged by the CLE results from the BIIB059 Phase 2 lupus study presented at the 2020 virtual EULAR congress," said Nathalie Franchimont, M.D., Ph.D., vice president of the multiple sclerosis and immunology development unit at Biogen. "These data underscore our goal of delivering meaningful new therapies to people living with lupus, who currently have limited treatment options."

The CLE part of the LILAC study met its primary endpoint ($p<0.001$) by demonstrating a dose response of BIIB059 on the percent change from baseline in the Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity (CLASI-A) score at week 16 in people with CLE. Study participants with CLE that received 50 mg, 150 mg and 450 mg of BIIB059 experienced reductions in CLASI-A scores of 38.8 percent ($p=0.015$), 47.9 percent ($p<0.001$) and 42.5 percent ($p=0.001$), respectively, versus 14.5 percent with placebo. CLASI-A is a well-defined and reliable outcome measure that has been shown to detect change in CLE skin disease activity.

With respect to the secondary endpoint of CLASI-50 response, statistical significance was achieved in study participants who received 450 mg of BIIB059; 23.3 percent ($p=0.024$) more participants achieved CLASI-50 response versus placebo. While not statistically significant, more participants treated with BIIB059 50 mg (15.8 percent) and 150 mg (21.2 percent) achieved a CLASI-50 response versus placebo. A CLASI-50 response is defined as a 50 percent improvement from baseline in CLASI-A score.

The majority of adverse events in the LILAC study were mild or moderate and the incidence of serious adverse events was 7.1 percent versus 9.1 percent in participants that received BIIB059 versus placebo. Rate of infections was 34.3 percent versus 30.3 percent in participants that received BIIB059 versus those given placebo; no significant increased risk of infection has been identified. Eight participants, who all received BIIB059, discontinued study drug due to side effects. Overall, the safety and tolerability results further support the continued development of BIIB059.

LILAC was a randomized, parallel, double-blind, placebo-controlled two-part study that evaluated BIIB059 versus placebo in participants with active CLE, including chronic and subacute subtypes, with or without systemic manifestations and in participants with systemic lupus erythematosus (SLE) with active joint and skin manifestations.

Final results from the SLE part of the LILAC study will be presented at a future medical congress.

About BIIB059
BIIB059, discovered and developed exclusively by Biogen, is an investigational fully humanized IgG1 monoclonal antibody (mAb) targeting blood dendritic cell antigen 2 (BDCA2) currently being evaluated for the treatment of CLE and SLE. BDCA2 is a receptor that is uniquely expressed on a subset of human immune cells called plasmacytoid dendritic cells (pDCs), and it has been shown to reduce inflammatory cytokine production from pDCs, including type-I IFN (IFN-I). Inflammatory mediators are thought to play a major role in the pathogenesis of lupus.

About the Phase 2 LILAC Study
The Phase 2 LILAC study (NCT02847598) was a randomized, parallel, double-blind, placebo-controlled two-part study that enrolled 264 participants to evaluate the safety and efficacy of BIIB059 versus placebo in participants with active CLE, including chronic and subacute subtypes, with or without systemic manifestations and in participants with SLE with active joint and skin manifestations.

The CLE part of the study, which enrolled 132 participants, investigated either a BIIB059 50 mg, 150 mg or 450 mg dose administered subcutaneously every 4 weeks with an additional dose at week 2 versus placebo in participants with active CLE. The primary endpoint was dose-response of BIIB059 as measured by percent change from baseline in the CLASI-A Score at Week 16.

About Cutaneous Lupus Erythematosus (CLE)
CLE is a chronic autoimmune disease where the body's immune system attacks healthy skin, often causing rashes and skin lesions which can be painful or itchy. CLE is associated with a decrease in quality of life and increased depression. In some of the chronic forms of the disease, people may experience scarring, skin atrophy and alopecia.

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 as well as related therapeutic adjacencies. 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. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, immunology, neurocognitive disorders, acute neurology and pain.

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Biogen Safe Harbor Statement
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements about the results of the Phase 2 LILAC study; the potential effects of BIIB059; the potential benefits, safety and efficacy of BIIB059; the clinical development program for BIIB059; the potential of our commercial business and pipeline programs, including BIIB059; data readouts and presentations related to BIIB059; the treatment of autoimmune diseases; our strategy and plans; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "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 risks relating to uncertainty of success in the development and potential commercialization of BIIB059; the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis; failure to obtain regulatory approvals; risks of unexpected hurdles, costs or delays; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; regulatory authorities may require additional information or further studies or may fail or refuse to approve or may delay approval of our drug candidates, including BIIB059; product liability claims; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this news release. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

MEDIA CONTACT:
David Caouette
+1 617 679 4945
public.affairs@biogen.com

INVESTOR CONTACT:
Joe Mara
+1 781 464 2442
IR@biogen.com