Biogen to Present Positive Phase 2 Systemic Lupus Erythematosus Data at American College of Rheumatology 2020 Meeting

November 3, 2020

- In Phase 2 LILAC study, BIIB059 demonstrated a statistically significant reduction in joint disease activity compared to placebo in systemic lupus erythematosus patients
- Positive results build on previously reported cutaneous lupus erythematosus data and underscore Biogen's commitment to the lupus community
- Systemic lupus erythematosus is a chronic and debilitating autoimmune disease that affects multiple organ systems, with periods of illness or flares alternating with periods of remission

CAMBRIDGE, Mass., Nov. 03, 2020 (GLOBE NEWSWIRE) -- Today, Biogen Inc. (Nasdaq: BIIB) announced positive data from the 24-week systemic lupus erythematosus (SLE) portion of the Phase 2 LILAC study (part A) demonstrating that BIIB059 (anti-BDCA2) was associated with a statistically significant reduction in total active joint count. The study evaluated the efficacy and safety of BIIB059, a humanized IgG1 monoclonal antibody (mAb) targeting blood dendritic cell antigen 2 (BDCA2) expressed exclusively on plasmacytoid dendritic cells. These data, along with the previously reported findings from the cutaneous lupus erythematosus (CLE) portion of the LILAC study, will be presented at the American College of Rheumatology's ACR Convergence 2020, being held virtually from November 5-9, 2020.

"People living with systemic lupus erythematosus suffer from chronic and debilitating symptoms that impact multiple organ systems as well as their social and emotional well-being," said Nathalie Franchimont, M.D., Ph.D., Vice President and Head of the Multiple Sclerosis and Immunology Development Unit at Biogen. "These latest data highlight the potential of BIIB059 to impact disease activity and, together with the earlier cutaneous lupus erythematosus findings, reflect Biogen's commitment to drive therapeutic innovation for lupus patients who have limited treatment options."

The Phase 2 LILAC study (part A) met its primary endpoint of reducing joint disease activity in individuals with SLE, as measured by total active joint count. A statistically significant difference in change from baseline of 3.4 in total active joint count was observed at week 24 between participants who received BIIB059 450 mg administered subcutaneously every 4 weeks with an additional dose at week 2 versus placebo (p=0.037). Total active joint count is the total number of tender or swollen joints. Tender or swollen joints are one of the most common symptoms impacting quality of life in people living with SLE.

The study also met the secondary endpoint of SLE Responder Index-4 (SRI-4), resulting in an overall reduction in disease activity in participants who received BIIB059 versus placebo. There was a 26.35 percent higher SRI-4 response rate among participants who received BIIB059 (56.77 percent) versus placebo (30.42 percent [odds ratio=3.49, p=0.003]). The SRI-4 is a composite measure comprising criteria from different internationally validated indices of systemic disease activity.

An additional secondary endpoint from part A of the study in individuals with SLE evaluated the effect of BIIB059 on skin disease activity using the CLE Activity Disease Area and Severity Index-Activity (CLASI-A) score in a subgroup of participants with a baseline CLASI-A score of ≥8. There was a 20 percent higher response rate among participants who received BIIB059 (69.10 percent) versus placebo (49.10 percent) who achieved at least 50 percent improvement (CLASI-50 response), however statistical significance was not attained (odds ratio=2.51, p=0.064). CLASI-A is a clinical tool that measures disease activity and damage in CLE.

The majority of adverse events in the LILAC study were mild or moderate. The incidence of serious adverse events was 5.3 percent versus 10.7 percent in participants that received BIIB059 versus placebo, respectively. Adverse events that led to drug discontinuation were observed in two participants who received BIIB059 and three participants who received placebo. Overall, the efficacy, safety and tolerability results further support the continued clinical development of BIIB059 in SLE.

Biogen Presentations Featured at ACR Convergence 2020:

- Plenary presentation (Plenary Session II, abstract 0935): Efficacy and Safety Results from a Phase 2, Randomized, Double-Blind Trial of BIIB059, an Anti-Blood Dendritic Cell Antigen 2 Antibody, in SLE – *Saturday, November 7, 11:45 am – 12:00 pm Eastern Time (ET)*
- Oral presentation (SLE – Treatment Session, abstract 0986): BIIB059, a Humanized Monoclonal Antibody Binding to BDCA2 on Plasmacytoid Dendritic Cells Shows Efficacy in a Phase 2 Study in Participants with Active Cutaneous Lupus Erythematosus – *Saturday, November 7, 3:10 pm – 3:20 pm ET*

About BIIB059
BIIB059, discovered and developed exclusively by Biogen, is a humanized IgG1 monoclonal antibody (mAb) targeting blood dendritic cell antigen 2 (BDCA2) and is being investigated for the treatment of cutaneous lupus erythematosus (CLE) and systemic lupus erythematosus (SLE). BDCA2 is a receptor that is exclusively 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. Biogen is currently planning to initiate a Phase 3 program for BIIB059.

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

The SLE part of the study, which enrolled 132 patients, evaluated a BIIB059 450 mg dose versus placebo injected subcutaneously once every four weeks with an additional dose at week 2 in individuals with active SLE. The primary endpoint was change from baseline in total active joint count at Week 24.

About Systemic Lupus Erythematosus (SLE) and Cutaneous Lupus Erythematosus (CLE)
SLE is a chronic autoimmune disease that affects multiple organ systems, with periods of illness or flares alternating with periods of remission. SLE can present itself in several ways including rash, arthritis, anemia, thrombocytopenia, serositis, nephritis, seizures or psychosis. SLE is associated with a greater risk of death from causes such as infection and cardiovascular disease.

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 forms of the disease, patients may experience scarring, skin atrophy and alopecia. CLE may occur in the presence of, or more frequently, in the absence of systemic disease.

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.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

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, about the results of the Phase 2 LILAC study of BIIB059; the potential clinical 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; our strategy and plans; the potential of our commercial business and pipeline programs, including BIIB059; 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.

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