Swissmedic Grants Good Manufacturing Practice Multi-Product License to Biogen Biologics Facility in Solothurn, Switzerland

May 20, 2021

CAMBRIDGE, Mass., May 20, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that its next generation manufacturing facility in Solothurn, Switzerland has received a Good Manufacturing Practice (GMP) multi-product license from the Swiss Agency for Therapeutic Products (SWISSMEDIC).

The Solothurn facility combines Biogen's latest concepts for fed-batch cell culture technology and protein purification, enabling the large-scale production of biopharmaceuticals. With more than 500 employees, the highly modernized facility design consists of multiple bio-manufacturing cells (BMCs) with site infrastructure in place to support future BMCs if needed. The GMP licensure is an important step in the readiness of the site, which enables the future submissions of product files to regulatory authorities. Notably, the site could support the manufacturing of aducanumab if approved, expanding on Biogen's existing capacity in Research Triangle Park, North Carolina, as well as the potential manufacturing of lecanemab (BAN2401) and other biologic assets.

"GMP licensure is a foundational and critical step forward towards our Solothurn manufacturing site creating, safeguarding and supplying high quality medicine to patients," said Nicole Murphy, Head of Global Manufacturing and Technical Operations at Biogen. "We are excited about the potential of our state-of-the-art manufacturing site in Switzerland where innovation is driven by our highly talented workforce."

As part of Biogen's sustainability goals, the Solothurn facility has implemented design features to keep emissions to the lowest level possible with the goal to become fossil fuel free by 2040. The building design and equipment will help to generate 83% fewer carbon emissions, will lower energy consumption by 79% and will reduce water usage per kilogram of output by 89%.

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, neuropsychiatry, immunology, acute neurology and neuropathic 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
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, relating to our Solothurn manufacturing facility; the anticipated benefits and potential of our Solothurn manufacturing facility; potential regulatory discussions, submissions and approvals and the timing thereof; the potential of our commercial business and pipeline programs, including aducanumab and lecanemab; risks and uncertainties associated with drug development and commercialization; our strategy and plans; results that may be achieved through our environmental, sustainability and corporate responsibility initiatives; and the anticipated timeline of our environmental, sustainability and corporate responsibility initiatives. These forward-looking statements may be identified 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. You should not place undue reliance on these statements.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation, uncertainty as to whether the anticipated benefits of our Solothurn manufacturing facility can be achieved; risks of unexpected hurdles, costs or delays; failure to obtain regulatory approvals; risks relating to investment in our manufacturing capacity; problems with our manufacturing processes; actual timing and content of submissions to and decisions made by the regulatory authorities; 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 our drug candidates, including aducanumab; risks that the goals of our environmental, sustainability and corporate responsibility initiatives will be completed in a timely manner or at all; 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:
Mike Hencke
+1 781 464-2442
IR@biogen.com