Biogen Completes Acquisition of Reata Pharmaceuticals

September 26, 2023

- Reata acquisition bolsters Biogen's rare disease portfolio with the addition of SKYCLARYS ® (omaveloxolone), the first and only FDA approved treatment for Friedreich's ataxia in the U.S.

CAMBRIDGE, Mass., Sept. 26, 2023 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) – has completed the acquisition of Reata Pharmaceuticals, Inc. (Nasdaq: RETA), a company focused on developing therapeutics that regulate cellular metabolism and inflammation in serious neurologic diseases. As a result of the transaction, Biogen has now acquired SKYCLARYS® (omaveloxolone), as well as other clinical and preclinical pipeline programs.

SKYCLARYS®, Reata Pharmaceuticals' lead asset, was approved for the treatment of Friedreich's ataxia (FA), a rare neuromuscular disorder, in the United States earlier this year. FA is genetic, progressive, life-shortening, debilitating, and degenerative, affecting an estimated 5,000 diagnosed patients within the United States[1]. The commercial launch of SKYCLARYS® is underway in the United States and European regulatory review is ongoing. As of the closing date, over 1,000 patient start forms for SKYCLARYS® have been submitted in the United States.

"By adding a highly complementary product in an area of significant unmet medical need to our portfolio, we believe the acquisition of Reata aligns with our strategy to serve patients, drive sustainable growth and create significant shareholder value," said Christopher A. Viehbacher, President and Chief Executive Officer at Biogen. "With the transaction now complete, we look forward to leveraging Biogen's rare disease expertise and capabilities to work together with our Reata colleagues as one team to bring SKYCLARYS® to patients living with this devastating disease."

Biogen anticipates significant synergies with its existing rare disease portfolio and plans to update its Full Year 2023 Financial Guidance in conjunction with its third quarter 2023 earnings release. The acquisition of Reata is expected to be slightly dilutive to Biogen's Non-GAAP diluted Earnings Per Share (EPS) in 2023, roughly neutral in 2024, and significantly accretive beginning in 2025, inclusive of associated transaction costs. As a result of the transaction closing, Reata's Class A common stock will no longer be listed for trading on the Nasdaq Global Market.

About SKYCLARYS® (omaveloxolone)
SKYCLARYS® (omaveloxolone) is an oral, 150 mg once-daily medication indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older in the United States. Additionally, the company's Marketing Authorization Application for omaveloxolone is under review in Europe by the European Medicines Agency (EMA). The European Commission has granted Orphan Drug designation in Europe to omaveloxolone for the treatment of Friedreich's ataxia.

About Biogen
Founded in 1978, Biogen is a leading global biotechnology company that has pioneered multiple breakthrough innovations including a broad portfolio of medicines to treat multiple sclerosis, the first approved treatment for spinal muscular atrophy, and two co-developed treatments to address a defining pathology of Alzheimer's disease. Biogen is advancing a pipeline of potential novel therapies across neurology, neuropsychiatry, specialized immunology and rare diseases and remains acutely focused on its purpose of serving humanity through science while advancing a healthier, more sustainable and equitable world.

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

Biogen Safe Harbor
This press release contains forward-looking statements, relating to: the anticipated benefits of the Reata Pharmaceuticals acquisition, our strategy and our future financial and operating results. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "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.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: our dependence on sales from our products; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; our dependence on collaborators, joint venture partners, and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; the potential impact of the conflict in Ukraine; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to technology failures or breaches; problems with our manufacturing processes; risks relating to management and personnel changes, including attracting and retaining personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; results of operations and financial condition; fluctuations in our operating results; risks related to investment in properties; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs;

risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission.

These statements speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

References:

1. Lynch DR, et al., Safety and Efficacy of Omaveloxolone in Friedreich Ataxia (MOXIe Study). Ann Neurol. 2021 Feb;89(2):212-225. doi: 10.1002/ana.25934

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