Pfizer Logo

Biogen to Acquire Novel Clinical Stage Asset with Application in Alzheimer's Disease and Parkinson's Disease from Pfizer Inc.

Monday, January 13, 2020 - 08:00am

• *PF-05251749 is a CNS-penetrant regulator of circadian rhythm with potential to address behavioral and neurological symptoms across various psychiatric and neurological diseases*

• *Biogen to pay Pfizer $75 million upfront plus potential milestones of up to $635 million, and royalties*

• *PF-05251749 complements the Company's pipeline of potential disease-modifying therapies for Alzheimer's and Parkinson's diseases*

CAMBRIDGE, Mass., -- Jan. 13, 2020 – Biogen Inc. (Nasdaq: BIIB) today announced an agreement to acquire from Pfizer Inc. (NYSE: PFE) PF-05251749, a novel CNS-penetrant small molecule inhibitor of casein kinase 1 (CK1), for the potential treatment of patients with behavioral and neurological symptoms across various psychiatric and neurological diseases. In particular, Biogen plans to develop the Phase 1 asset for the treatment of Sundowning in Alzheimer's disease (AD) and Irregular Sleep Wake Rhythm Disorder (ISWRD) in Parkinson's disease (PD). The purchase will include an upfront payment of $75 million with up to $635 million in potential additional development and commercialization milestone payments, as well as tiered royalties in the high single digits to sub-teens.

"This asset is highly complementary to our existing pipeline of potential disease-modifying therapies in Alzheimer's and Parkinson's diseases," said Alfred Sandrock Jr., M.D., Ph.D., Executive Vice President, Research and Development and Chief Medical Officer at Biogen. "Many patients with Alzheimer's and Parkinson's suffer from debilitating sleep disorders and agitation, and we believe that the regulation of the circadian rhythm may hold promise in addressing these challenging behavioral and neurological symptoms."

CK1 is a key regulator of the 'central clock,' the suprachiasmatic nucleus of the hypothalamus, that controls circadian rhythm and impacts nearly all vital physiology and metabolism. The disruption of circadian rhythm is associated with various psychiatric and neurological diseases, including certain important symptoms of AD and PD.

Sundowning is a symptom that impacts 20% or more of AD patients who become confused, anxious, aggressive, agitated or restless later in the day. ISWRD is a circadian rhythm disorder where patients experience fragmented nighttime sleep leading to daytime sleepiness, severe fatigue and difficulty with activities of daily living. It is one of the non-motor symptoms of PD, and usually increases in frequency over the course of the disease and disability progression. Biogen will explore the potential of PF-05251749 to improve behavioral disturbances of Sundowning in AD by correcting circadian rhythm, as well as its potential to treat symptoms of ISWRD to

improve daytime wakefulness, sleep quality, behavior and daily function.

PF-05251749 has previously demonstrated an acceptable safety profile and proof of mechanism in a Phase 1a clinical study. Biogen aims to initiate a Phase 1b study in Q4 2020.

This transaction will be accounted for as an asset acquisition and is subject to customary closing conditions, including the expiration of the applicable waiting period under the Hart Scott Rodino Antitrust Improvements Act of 1976 in the United States.

Biogen expects the transaction to close in the first quarter of 2020.

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. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Safe Harbor
This news release contains forward-looking statements, made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements relating to the potential benefits and results that may be achieved through the proposed transaction with Pfizer; the anticipated completion and timing of the proposed transaction; the potential benefits, safety and efficacy of PF-05251749; the clinical development program for PF-05251749; the potential of our commercial business and pipeline programs; 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," "potential," "possible," "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 that the proposed transaction will be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits of the proposed transaction can be achieved; risks of unexpected hurdles, costs or delays; uncertainty of success in the development and potential commercialization of PF-05251749, which may be impacted by, among other things, unexpected concerns that may arise from additional data or analysis, the occurrence of adverse safety events, failure to obtain regulatory approvals in certain jurisdictions, failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; and third party collaboration risks. 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 risks 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.

###

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

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