Biogen and Alkermes Announce License and Collaboration Agreement to Develop and Commercialize ALKS 8700 for the Treatment of Multiple Sclerosis

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— Novel, Oral, Fumarate Therapy Intended to Provide a Differentiated Gastrointestinal Tolerability Profile —

— Biogen Brings Multiple Sclerosis Expertise to Commercialization of ALKS 8700 —

— New Drug Application Anticipated for Submission in 2018 —

CAMBRIDGE, Mass. & DUBLIN--(BUSINESS WIRE)--Nov. 27, 2017-- Biogen (Nasdaq:BIIB) and Alkermes plc (Nasdaq:ALKS) today announced that they have entered into a global license and collaboration agreement to develop and commercialize ALKS 8700, a novel, oral, monomethyl fumarate (MMF) small drug molecule in Phase 3 development for the treatment of relapsing forms of multiple sclerosis (MS).

“This partnership is further evidence of Biogen’s ongoing commitment to multiple sclerosis and builds upon our deep experience in neuroscience and particularly in MS,” stated Michel Vounatsos, Chief Executive Officer at Biogen. “We aim to provide patients with a new oral therapy which may bring differentiated benefits.”

“This collaboration has the potential to provide important benefits to patients with multiple sclerosis and immediately increases the value of ALKS 8700 to Alkermes,” said Richard Pops, Chief Executive Officer at Alkermes. “Biogen has a broad product portfolio and a highly experienced commercial team. In Biogen’s hands, we believe that patients will have broader and more rapid access to this important medicine. Meanwhile, we will focus our growing commercial capabilities on our expanding portfolio of medicines in psychiatry, including addiction, schizophrenia and depression.”

Under the terms of the agreement, Biogen will receive an exclusive, worldwide license to commercialize ALKS 8700 and will pay Alkermes a mid-teens royalty on worldwide net sales of ALKS 8700.

This collaboration aligns the interests of Alkermes and Biogen in the successful development and commercialization of ALKS 8700 as an important potential treatment option for patients suffering from MS. Biogen will reimburse Alkermes for fifty percent (50%) of the 2017 ALKS 8700 development costs, with Alkermes receiving an upfront payment of $28 million representing Biogen’s share of development expenses already incurred in 2017. Beginning Jan. 1, 2018, Biogen will be responsible for all development expenses related to ALKS 8700. Alkermes may also receive milestone payments for ALKS 8700 with a maximum aggregate value of $200 million upon certain clinical and regulatory achievements. Biogen anticipates the initial milestone payment of $50 million will be recorded as an expense in 2017.

Alkermes will maintain responsibility for regulatory interactions with the U.S. Food and Drug Administration (FDA) through the potential approval of the New Drug Application (NDA) for ALKS 8700 for the treatment of MS. Biogen shall be responsible for all commercialization activities for ALKS 8700.

ALKS 8700 is currently in Phase 3 development for MS. Alkermes plans to seek approval of ALKS 8700 under the 505(b)(2) regulatory pathway referencing Biogen’s TECFIDERA ® (dimethyl fumarate). The registration package for ALKS 8700 will include pharmacokinetic bridging studies that establish bioequivalence to TECFIDERA and data from a two-year safety study known as EVOLVE-MS-1. Initial safety data from EVOLVE-MS-1 were recently presented at MSParis2017, the 7th Joint Meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) in October. Safety data from the first month of the EVOLVE-MS-1 study (N=580) showed that treatment with ALKS 8700 was associated with low rates of gastrointestinal (GI) adverse events (AEs) leading to discontinuation and no occurrence of serious GI AEs. The most common AEs during the first month of treatment with ALKS 8700 were flushing, pruritus and diarrhea.

Also, currently underway is a head-to-head study (EVOLVE-MS-2) evaluating the GI tolerability of ALKS 8700 compared to TECFIDERA. Initial data from EVOLVE-MS-2 are expected in the first half of 2018.

About the EVOLVE-MS Clinical Development Program

The key components of the EVOLVE-MS (Endeavoring to Advance Treatment for Patients Living with Multiple Sclerosis) clinical development program of ALKS 8700 include a two-year safety study and pharmacokinetic bridging studies comparing ALKS 8700 and TECFIDERA. In addition, the program includes an elective head-to-head study comparing the GI tolerability of ALKS 8700 and TECFIDERA.

About ALKS 8700

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate (MMF) prodrug candidate in development for the treatment of relapsing forms of multiple sclerosis (MS). ALKS 8700 is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA®.

About Multiple Sclerosis

Multiple sclerosis (MS) is an unpredictable, often disabling disease of the central nervous system (CNS), which interrupts the flow of information within the brain, and between the brain and body.[1] MS symptoms can vary over time and from person to person. Symptoms may include extreme fatigue, impaired vision, problems with balance and walking, numbness or pain and other sensory changes, bladder and bowel symptoms, tremors, problems with memory and concentration and mood changes, among others.[1]Approximately 400,000 individuals in the U.S. and 2.5 million people worldwide have MS, and most are diagnosed between the ages of 15 and 50.[2]

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

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. Founded in 1978 as one of the world's first global biotechnology companies by Charles Weissman, 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 and only approved treatment for spinal muscular atrophy; and is focused on advancing neuroscience research programs in Alzheimer's disease and dementia, neuroimmunology, movement disorders, neuromuscular disorders, pain, ophthalmology, neuropsychiatry, and acute neurology. Biogen also manufactures and commercializes biosimilars of advanced biologics.

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.

Biogen Safe Harbor

This press 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, including financial and operating results, that may be achieved through Biogen's license agreement with Alkermes, risks and uncertainties associated with drug development and commercialization, the potential benefits, safety, efficacy and clinical effects of ALKS 8700, the timing and status of regulatory filings, and the potential of Biogen's commercial business and pipeline programs, including ALKS 8700. These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will," 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: uncertainty as to whether the anticipated benefits and potential of Biogen's license agreement with Alkermes can be achieved; risks that Biogen and/or Alkermes may not fully enroll the clinical trials for ALKS 8700 or will take longer than expected; risks of unexpected costs or delays; uncertainty of success in the development and potential commercialization of ALKS 8700, 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 Biogen's data, intellectual property, and other proprietary rights and uncertainties relating to intellectual property claims and challenges; third party collaboration risks; and uncertainty of Biogen's success in developing, licensing, or acquiring other product candidates or additional indications for existing products. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this press release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

Alkermes Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the continued expansion of Alkermes' portfolio of medicines in psychiatry, the continued clinical development and the potential therapeutic and commercial value of ALKS 8700 for the treatment of relapsing forms of MS, the number of patients enrolled in the ALKS 8700 Phase 3 studies, the timing of expected initial data from EVOLVE-MS-2, the regulatory strategy for filing of an NDA for ALKS 8700 and the adequacy of the EVOLVE-MS development program for ALKS 8700 to serve as the basis for an NDA, the timing of the submission of an NDA to the FDA for ALKS 8700 and the potential financial, commercial and therapeutic benefits that may be achieved through collaboration with Biogen under the license and collaboration agreement between Alkermes and Biogen. Alkermes cautions that forward-looking statements are inherently uncertain. Although Alkermes believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether the results from the head-to-head study to evaluate the GI tolerability of ALKS 8700 compared to TECFIDERA will show that ALKS 8700 has more favorable GI tolerability; whether preclinical and early clinical results for ALKS 8700 will be predictive of future clinical study results or real-world results; whether clinical trials for ALKS 8700 will be completed on time or at all; changes in the cost, scope and duration of the ALKS 8700 clinical trials; whether ALKS 8700 could be shown ineffective or unsafe during clinical studies, and whether, in such instances, Alkermes may not be permitted by regulatory authorities to undertake new or additional clinical studies of ALKS 8700; whether regulatory submissions for ALKS 8700 will be submitted on time or at all; whether adverse decisions by regulatory authorities will occur; whether the pharmacokinetic, Phase 3 and other studies conducted for ALKS 8700 will meet the FDA's requirements for approval; whether the potential financial, commercial and therapeutic benefits of collaboration with Biogen under the license and collaboration agreement between Alkermes and Biogen will be achieved; and those risks described in the Alkermes Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and September 30, 2017 and in subsequent filings made by Alkermes with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

[1] National Multiple Sclerosis Society. *Multiple Sclerosis: Just the Facts*. Accessed from http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Brochure-Just-the-Facts.pdf on Nov. 27, 2017.

[2] Multiple Sclerosis Association of America. *MS Overview*. Accessed from http://mymsaa.org/ms-information/overview/who-gets-ms/ on Nov. 27, 2017.

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