



## **Alkermes Receives \$50 Million Payment From Biogen Following Review of Preliminary Gastrointestinal Tolerability Data From the Ongoing BIIB098 Clinical Development Program**

June 6, 2018

**-- Novel, Oral Fumarate Therapy Intended to Provide a Differentiated Gastrointestinal Tolerability Profile --  
-- New Drug Application Anticipated for Submission in Q4 2018 --**

DUBLIN, June 6, 2018 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today announced it has received a \$50 million payment from Biogen. This payment follows Biogen's review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for BIIB098 (diroximel fumarate). BIIB098 (formerly ALKS 8700) is a novel, oral fumarate in phase 3 development for the treatment of relapsing forms of multiple sclerosis (MS). Alkermes expects to submit a New Drug Application (NDA) for BIIB098 to the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2018.

"The clinical data generated from this program underscore the potential value of BIIB098 for patients with multiple sclerosis," said Richard Pops, Chief Executive Officer at Alkermes. "Our focus remains on completing the registration requirements and preparing the BIIB098 NDA for submission in the fourth quarter of 2018, as we advance this important potential new therapeutic option for patients with MS."

Substantially all of the payment will be recorded as License Revenue in Alkermes' financial results for the quarter ending June 30, 2018.

Under the terms of the license and collaboration agreement, Biogen has an exclusive, worldwide license to commercialize BIIB098 and will pay Alkermes a mid-teens percentage royalty on worldwide net sales. Alkermes may also receive a \$150 million milestone payment from Biogen upon FDA approval, on or before Dec. 31, 2021, of the NDA for BIIB098.

BIIB098 is currently in phase 3 development for relapsing forms of MS. Alkermes plans to seek approval of BIIB098 under the 505(b)(2) regulatory pathway referencing Biogen's TECFIDERA® (dimethyl fumarate). Alkermes' registration package for BIIB098 will include pharmacokinetic bridging studies to establish bioequivalence to dimethyl fumarate and data from a two-year safety study known as EVOLVE-MS-1.

### **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 BIIB098 include a two-year safety study and pharmacokinetic bridging studies comparing BIIB098 and dimethyl fumarate.

### **About BIIB098**

BIIB098 (diroximel fumarate) is an oral, novel fumarate candidate in development for the treatment of relapsing forms of multiple sclerosis (MS). BIIB098 is designed to rapidly and efficiently convert to monomethyl fumarate in the body and to potentially offer differentiated features as compared to dimethyl fumarate.

### **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.<sup>1</sup> 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.<sup>1</sup> 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.<sup>2</sup>

### **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](http://www.alkermes.com).

### **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 clinical development and the potential therapeutic and commercial value of BIIB098 for the treatment of relapsing forms of MS, the regulatory strategy for filing of an NDA for BIIB098 and the adequacy of the EVOLVE-MS development program for BIIB098 to serve as the basis for an NDA, the timing of the submission of an NDA to the FDA for BIIB098 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 BIIB098 compared to dimethyl fumarate will show that BIIB098 has more favorable GI tolerability; whether preclinical and early clinical results for BIIB098 will be predictive of future clinical study results or real-world results; whether clinical trials for BIIB098 will be completed on time or at all; changes in the cost, scope and duration of the BIIB098 clinical trials; whether BIIB098 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 BIIB098; whether regulatory submissions for BIIB098 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 BIIB098 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 Dec. 31, 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](http://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.

TECFIDERA® is a registered trademark of Biogen Inc.

<sup>1</sup> 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 June 5, 2018.

<sup>2</sup> Multiple Sclerosis Association of America. *MS Overview*. Accessed from <http://mymsaa.org/ms-information/overview/who-gets-ms/> on June 5, 2018.

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