



## **Alkermes to Present New Clinical Data on ALKS 8700 at MSParis2017, the 7th JointECTRIMS-ACTRIMS Meeting**

October 16, 2017

— *Safety and Gastrointestinal Tolerability Profile During Initial Three Months of ALKS 8700 Treatment in Ongoing Long-Term Safety Study to be Highlighted* —

DUBLIN--(BUSINESS WIRE)--Oct. 16, 2017-- [Alkermes plc](#) (NASDAQ: ALKS) today announced that two posters on ALKS 8700, a novel, oral monomethyl fumarate (MMF) prodrug candidate in development for the treatment of relapsing forms of multiple sclerosis (MS), will be presented at MSParis2017, the 7<sup>th</sup> 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), being held Oct. 25-28, 2017 in Paris, France. Interim safety and gastrointestinal (GI) tolerability data during the first three months of treatment with ALKS 8700 from the ongoing two-year, open-label, phase 3 safety study will be presented. A poster detailing the study design for the ongoing phase 3 GI tolerability study comparing ALKS 8700 to TECFIDERA® will also be presented.

"We designed ALKS 8700, a MMF prodrug with distinct physical-chemical properties, to harness the efficacy of monomethyl fumarate with a differentiated safety and tolerability profile," said Elliot Ehrich, M.D., Executive Vice President of Research and Development at Alkermes. "The presentations at MSParis2017 will provide additional insight into the emerging safety and tolerability profile of ALKS 8700 and the potential of ALKS 8700 to provide patients suffering from MS with an important treatment alternative."

Alkermes presentations at MSParis2017 will include:

- Poster #708, "EVOLVE-MS-2: A Randomized, Double-Blind, Phase 3 Study of the Gastrointestinal Tolerability of ALKS 8700 Versus Dimethyl Fumarate in Relapsing-Remitting Multiple Sclerosis," will describe the study design, preliminary patient demographics and baseline characteristics of an ongoing, elective head-to-head study evaluating ALKS 8700 vs. TECFIDERA during Poster Session I, Thursday, Oct. 26, 2017, 3:30 – 5:00 p.m. CEST.
- Poster #1170, "EVOLVE-MS-1: A Phase 3, Open-Label, Long-Term Safety Study of ALKS 8700 in Relapsing-Remitting Multiple Sclerosis," will describe patient demographics, baseline characteristics, and safety and GI tolerability data from the ongoing two-year, open-label safety study of ALKS 8700 during Poster Session II, Friday, Oct. 27, 2017, 3:30 – 5:00 p.m. CEST.

For more information, please visit the conference website at <https://www.ectrims-congress.eu/2017.html>.

### **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.<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**

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 therapeutic value of ALKS 8700

and the commercial potential of ALKS 8700. The company cautions that forward-looking statements are inherently uncertain. Although the company 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 favorable GI tolerability; whether preclinical and early clinical results for ALKS 8700 will be predictive of future clinical study 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 occur; whether the pharmacokinetic, phase 3 and other studies conducted for ALKS 8700 will meet the U.S. Food and Drug Administration's requirements; and those risks described in the Alkermes plc Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2016, and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and June 30, 2017 and in subsequent filings made by the company 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 MA 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 Oct. 13, 2017.

<sup>2</sup> Multiple Sclerosis Association of America. *MS Overview*. Accessed from <http://mymsaa.org/ms-information/overview/who-gets-ms/> on Oct. 13, 2017.

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