BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Biogen and Alkermes announce license and collaboration agreement

28 November 2017 | News

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

US based biotech company Biogen and pharma company Alkermes has 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).

Michel Vounatsos, Chief Executive Officer at Biogen said, “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. We aim to provide patients with a new oral therapy which may bring differentiated benefits.”

Richard Pops, Chief Executive Officer at Alkermes said, “This collaboration has the potential to provide important benefits to patients with multiple sclerosis and immediately increases the value of ALKS 8700 to 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.

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®.

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.

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.