Mapi Announces First Patient Enrolled in the Phase III Clinical Trial of GA Depot for Relapsing Multiple Sclerosis (RMS)

Ness Ziona, Israel, October 28, 2019 --- Mapi Pharma Ltd. announced today that the first patient has been enrolled in its Phase III study with GA Depot for relapsing forms of multiple sclerosis (RMS). Glatiramer acetate, the active material of Copaxone®, or its generic forms, is the most common treatment for RMS in the US. GA Depot is a long-acting depot formulation injection of glatiramer acetate administered once every four weeks, compared with the daily or thrice weekly regimen used with Copaxone® or its generic forms. In first year of the ongoing Phase II trial for RRMS, 84.6% of the per protocol patient population treated with GA Depot achieved NEDA-3 (No Evidence of Disease Activity, a composite parameter that combines no relapses, no new MRI or enhanced lesions and no confirmed disability progressions). The most advanced patients in that trial have started their sixth year of treatment. Three-year Phase II results were recently presented in September 2019 in the late breaking news session of ECTRIMS 2019 conference at Stockholm.

"Treating RMS is of great importance and there is a significant unmet need for a product such as a long acting Glatiramer Acetate, which has disease modifying potential, and appears safe and well tolerated. The ability to achieve reliable dosing by means of a once monthly dose schedule is expected to ensure adherence to the treatment. We hope the efficacy that was demonstrated in the Phase II study can be confirmed in the on-going Phase III," said the study's Principal Investigator Aaron Miller, MD Medical Director, Corinne Goldsmith Dickinson Center for Multiple Sclerosis, Professor and Vice Chair for Education, Department of Neurology, Icahn School of Medicine at Mount Sinai, New York.

Ehud Marom, CEO and Chairman of Mapi Pharma Ltd., commented, "Our goal is to develop and launch the best drug for MS, and we believe that GA Depot has a compelling profile, combining the safety of Copaxone with better efficacy and the potential for improved compliance. We believe that a product with these attributes will convince doctors, payers and MS patients to select it as a first choice treatment for RMS. Our GA Depot development program is part of Mapi's broader strategy to introduce long acting depot injections and other new drugs that provide improved treatment for MS patients."

Mylan President, Rajiv Malik, added, "We're pleased to partner with Mapi on this important product for MS patients and look forward to advancing to the Phase III clinical trials. We continue to be encouraged by the success of the scientific program to date and remain committed to bring GA Depot to market at the earliest opportunity."

Phase III Trial Design

The prospective, multinational, multicenter, randomized, Phase III, double-blind, parallel-group, placebo controlled study is designed to assess the efficacy, safety and tolerability of GA Depot in subjects with relapsing forms of multiple sclerosis (RMS). A total of 960 subjects are planned to be randomized into this study to receive treatment with GA Depot or with matching placebo. During the placebo-controlled period (the first 52 weeks of the study immediately after randomization), subjects will receive either 40mg of GA

Depot or matching placebo, via intramuscular injection (IM), once every 4 weeks for a total of 13 doses. Subjects who complete the initial placebo-controlled period will be given the option to continue into the open label period for an additional 52 weeks, in which all subjects will receive 40mg of GA Depot IM once every 4 weeks. The primary endpoint is annualized relapse rate (ARR) derived from the total number of confirmed relapses.

Link to Phase III in clinicaltrials.gov: https://clinicaltrials.gov/ct2/show/NCT04121221

About GA Depot

GA Depot is a long acting injection version of the approved Glatiramer Acetate (GA, commercially available as Copaxone®), designed to be administered as an intramuscular injection once every four weeks. GA Depot is intended to be used for treatment of relapsing forms of multiple sclerosis (RMS), and is currently evaluated in a multinational Phase III clinical study. GA Depot is also currently being tested in Phase II for primary progressive multiple sclerosis (PPMS).

About Mapi Pharma

Mapi is a clinical stage pharmaceutical company, engaged in the development of high barrier-to-entry and high added-value life cycle management ("LCM") products that target large markets and generic drugs that include complex active pharmaceutical ingredients ("APIs") and formulations. The GA Depot injection, administered once every four weeks, is the first in a series of depot long-acting injections in the company's pipeline, for the treatment of MS. The product is a LCM version of Copaxone®, which requires injections daily or every other day. Mapi Pharma partnered with Mylan N.V. (NASDAQ: MYL) for GA Depot in an agreement under which Mylan was granted an exclusive license to commercialize the GA Depot injection product for relapsing multiple sclerosis. Mapi is built on strong chemical and pharmaceutical R&D capabilities, a deep understanding of the global market and of regulatory needs. Mapi is headquartered in Israel, with R&D facilities in Israel and China, an API production facility in the Neot-Hovav Eco Industrial Park and an aseptic manufacturing and Fill & Finish for injectable Finished Dosage Form facility in Jerusalem. Mapi has a strong IP position, filing numerous patent applications for APIs and formulations. Mapi Pharma was founded by Ehud Marom who serves as Chairman & CEO of Mapi Pharma and Stem Cell Medicine and as the Chairman of Pharma Two B. For more information, please visit: www.mapi-pharma.com.

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