



Mapi Pharma Provides Enrollment Update in Phase III GA Depot Clinical Trial

Patient recruitment in Phase III trial has surpassed 60%

Trial is expanded to Israel with first clinical site at Tel Aviv Medical Center

NESS ZIONA, Israel – Dec. 21, 2020 – Mapi Pharma Ltd., a fully integrated, late clinical stage biopharmaceutical company, today announced that patient enrollment has surpassed 60% in the ongoing GA Depot (glatiramer acetate) Phase III trial for Relapsing forms of Multiple Sclerosis (RMS).

GA Depot is a long acting injection version of the approved Glatiramer Acetate products (Copaxone® and its generic versions) for treating multiple sclerosis (RMS), designed to be administered as an intramuscular injection once every four weeks. GA Depot is currently evaluated in a multinational Phase III clinical study and also in an international Phase II for Primary Progressive Multiple Sclerosis (PPMS).

The on-going Phase III study is a prospective, multinational, multicenter, randomized, double-blind, parallel-group, placebo controlled study 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 randomized into two groups in this study. During the placebo-controlled portion of the Phase III, subjects receive either 40mg of GA Depot or placebo, via intramuscular injection (IM), once every 4 weeks for a total of 13 doses. Subjects who complete the initial placebo-controlled period are 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.

As the recruitment to the study is progressing ahead of schedule, the Company is currently expanding the study into additional countries, including Israel. The first clinical site in Israel is the Tel Aviv Sourasky Medical Center.

Over 60% of the study subjects have been recruited, bringing the total number of patients dosed to over 600. The Multiple Sclerosis International Foundation (MSIF), established by MS neurologists and research experts, published guidelines on October 23, 2020, that glatiramer acetate, unlike other MS therapies, is unlikely to impact negatively on COVID-19 severity.

Ehud Marom, Chairman and Chief Executive Officer of Mapi, said, “We are very pleased with the recruitment rate into our Phase III study and our expectation now is that Last Patient In (LPI) will occur in the first half of 2021. In the first Data Monitoring Committee review no safety concerns were raised and the Committee (which acts independently) advised that the study should continue without modifications.”

The rights to GA Depot for use in RMS have been exclusively licensed to Viatriis (formerly Mylan) to commercialize the product.

Rajiv Malik, President of Viatriis, commented, “Viatriis is uniquely positioned to increase access to healthcare and address unmet needs for patients around the world, including those living with MS. We are encouraged by the progress of this trial and in parallel continue to advance commercial operations and supply chain planning in order to bring GA Depot to market at the earliest opportunity. We look forward



to expanding our MS portfolio through our strong collaboration with Mapi and increasing access to treatment for those who need it.”

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 Viatrix (NASDAQ: VTRS, formerly Mylan) for GA Depot in an agreement under which Viatrix was granted an exclusive license to commercialize the GA Depot injection product for relapsing forms of 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 a Fill & Finish facility for injectable Finished Dosage Forms 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. For more information, please visit: www.mapi-pharma.com.

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