



Mapi Pharma and Mylan Strengthen Partnership to Develop and Commercialize Once-Monthly Glatiramer Acetate Depot for Relapsing-Remitting Forms of Multiple Sclerosis

Mylan to invest an additional \$20M in Mapi Pharma in support of continued progress on Phase 3 clinical studies

NESS ZIONA, Israel, June 15, 2020 -- Mapi Pharma Ltd., a privately held, fully integrated, late clinical stage biopharmaceutical company today announced an additional \$20 million investment from Mylan in support of continued Phase 3 clinical study progress to bring to market in the U.S. Glatiramer Acetate (GA) Depot, a proposed once-monthly injection for the treatment of patients with relapsing-remitting multiple sclerosis (RRMS).

In October 2019, Mapi Pharma initiated the Phase 3 study¹ for relapsing-remitting multiple sclerosis, or RRMS, which is a 1,000 patient pivotal clinical study designed to support a New Drug Application (NDA) with the U.S. Food and Drug Administration. To date, the study enrollment has been progressing well with more than 170 patients dosed across 56 sites. In parallel, Mapi is also building capacity at its facility to supply GA-Depot for commercial sale, pending final approval by the FDA.

Multiple sclerosis (MS) organizations have estimated that 2.3 million individuals are living with MS worldwide. In the U.S., a study funded by the National MS Society estimates that nearly 1 million people are living with MS. Relapsing-remitting MS accounts for approximately 85% of initial MS diagnoses. According to recent market research, the global multiple sclerosis drugs market was worth US\$23 billion in 2018 and is anticipated to expand at a CAGR of 6.7%, and reach US\$39 billion by the end of 2026.

“Mapi Pharma and Mylan share a commitment to improve the lives of MS patients, and I am pleased that Mylan has expressed its continued confidence in our development program for GA-Depot for RRMS,” said Ehud Marom, Chairman and CEO of Mapi. “Through this partnership, and based on the excellent progress to date in launching the Phase 3 study and enrolling patients, we are confident in our ability to successfully bring to market our GA-Depot product.”

Mylan President Rajiv Malik commented: “Mylan is committed to meeting unmet needs by continuing to leverage its partnerships, scientific and commercial expertise and global platform to advance new treatment options for patients living with MS. Through this latest equity participation in Mapi, we are further strengthening our partnership and remain highly confident in the science and the progress of the program behind this long-acting GA product. We look forward to the Phase 3 study outcomes and are committed to bringing GA Depot to market at the

¹ For more information on the Phase 3 study, refer to ClinicalTrials.gov Identifier: NCT04121221.



earliest opportunity in order to bolster our already comprehensive MS offering in the U.S., including Glatiramer Acetate 20 mg/mL and 40 mg/mL.”

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 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 and as the Chairman of Pharma Two B. For more information, please visit: www.mapi-pharma.com.

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