

# Mapi Pharma to Present Plans for Additional Studies of GA Depot in Multiple Sclerosis and Other Indications and Highlights Latest Results on GA Depot in Relapsing Multiple Sclerosis at the ECTRIMS-ACTRIMS<sup>®</sup> Meeting in Milan, Italy October 11-13, 2023

# Meeting to feature latest clinical findings on GA Depot and showcase commitment to improving care for people living with multiple sclerosis (MS)

NESS ZIONA, Israel – Oct. 10, 2023 – Mapi Pharma Ltd., a fully integrated, late-stage clinical development biopharmaceutical company focused on introducing innovative long-acting depot injectable solutions mainly for neurological indications, announced today that recent clinical data from studies of GA Depot 40 mg will be presented at the forthcoming <u>European Committee for Treatment and Research in Multiple Sclerosis & Americas Committee for Treatment and Research in Multiple Sclerosis</u> (ECTRIMS-ACTRIMS) meeting to take place in Milan, Italy, October 11 to 13.

Data include improved safety and tolerability features from the pivotal Phase 3 clinical trial evaluating the efficacy and safety of GA Depot – a long-acting glatiramer acetate being investigated as a once-monthly injection for the treatment of relapsing forms of multiple sclerosis (RMS).

Multiple sclerosis (MS) is a chronic disease requiring lifelong therapy. Glatiramer acetate (GA) long-acting injection (GA Depot) consists of extended-release GA, administered once every 28 days. GA Depot significantly reduced the rate of MS relapses and the number of newly enhanced lesions in a double-blind, randomized, placebo-controlled Phase 3 study in subjects with relapsing forms of MS.

"The data presented at this year's ECTRIMS-ACTRIMS Congress (MS Milan) show that GA Depot has a favorable safety and tolerability profile compared to daily or thrice weekly GA formulations and may have a safety advantage compared to available treatments. If approved, GA Depot may increase patient adherence and improve patients' quality of life and has the potential to be a first line therapy for relapsing forms of multiple sclerosis," said the study's Principal Investigator Aaron Miller, M.D., Medical Director, Corinne Goldsmith Dickinson Center for Multiple Sclerosis, Department of Neurology, Icahn School of Medicine at Mount Sinai, New York.

Ehud Marom, Chairman and Chief Executive Officer, Mapi Pharma said "We are progressing with our New Drug Application for GA Depot for the treatment of RMS. The ECTRIMS-ACTRIMS meeting is an important forum to share with the neurological and investor community that GA Depot may offer an effective treatment option to patients with relapsing forms of multiple sclerosis."

"Based on the positive results from the Phase 3 in RMS and the strong efficacy data in Phase 2 in PPMS which were published in 2022, Mapi Pharma is planning to raise \$100 million to fund a Phase 3 study of GA Depot for PPMS and more Phase 3 studies in other indications based on our Depot Technology," added Mr. Marom.

Mapi will be attending the Jefferies Healthcare Conference in London, November 14-16, 2023, and the 42<sup>nd</sup> Annual JP Morgan Healthcare Conference to take place in San Francisco, January 8-11, 2024.



#### **About Mapi Pharma**

Mapi Pharma is a clinical stage pharmaceutical company, engaged in development of high barrier-to-entry and high added-value life cycle management ("LCM") products and AB Rated Depot injectable products that target large markets that include complex active pharmaceutical ingredients ("APIs") and formulations. Mapi Pharma's lead product is GA Depot which is partnered with Viatris (NASDAQ: VTRS) in an agreement under which Viatris was granted an exclusive license to commercialize the GA Depot injection product for Relapsing Forms of Multiple Sclerosis (RMS). Following successful Phase 3 results FDA assigned the PDUFA target action date of March 8, 2024, for GA Depot. The Company is also marketing its own generic versions of Fingolimod (Gilenya®) and Apremilast (Otezla®) in specific geographic markets. Mapi's portfolio also includes a leading development of Depot drugs for Schizophrenia, GLP-1 for diabetes, weight control, Parkinson's disease and potentially Alzheimer's with innovative intellectual property. Mapi is built on strong chemical and pharmaceutical R&D capabilities and a deep understanding of the global market and of regulatory needs. Mapi is a global company with a Depot R&D center, API production and aseptic Depot manufacturing and a Fill & Finish for injectable Finished Dosage Forms facilities. Mapi has strong IP positions, filing numerous patent applications for APIs and formulations. For more information, please visit www.mapi-pharma.com

## **About GA Depot**

GA Depot is a long-acting injection version of the approved Glatiramer Acetate (GA, commercially available as Copaxone<sup>®</sup>/Glatopa<sup>®</sup>), 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). GA Depot, which successfully completed a Phase 3 study for Relapsing forms of Multiple Sclerosis (RMS) and is now in FDA review is also currently being tested in Phase 2 for Primary Progressive Multiple Sclerosis (PPMS).

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