



## **Mapi Pharma Presents Glatiramer Acetate Depot (GA Depot) Results at the 8<sup>th</sup> Joint ACTRIMS-ECTRIMS Meeting MSVirtual2020**

90% of relapsing remitting multiple sclerosis (RRMS) patients on GA Depot demonstrated no evidence of disease activity (NEDA) at four years

Data suggest that GA Depot may also have potential as a primary progressive multiple sclerosis (PPMS) treatment

**NESS ZIONA, Israel – Sep. 10<sup>th</sup>, 2020** – Mapi Pharma Ltd., a fully integrated, late-stage clinical development biopharmaceutical company, today announced that it will present data from its ongoing Phase II studies of GA Depot for the treatment of relapsing remitting multiple sclerosis (RRMS) and primary progressive multiple sclerosis (PPMS) at MS Virtual 2020, the 8<sup>th</sup> Joint Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS-ECTRIMS), which will take place virtually on September 11-13.

In the RRMS extension phase II study, all participants received a 40mg dose of GA Depot once every four weeks for the 52-week core study period. Adverse events (AEs) mainly included mild injection site reactions, and no unexpected AEs were reported. Subjects who completed 13 injections were able to enter the optional extension study. The number of AEs was significantly reduced during the extension study compared to the core study, particularly during the fourth extension year as compared to the first two years of the study. No systemic immediate post-injection reactions were detected. Mean Expanded Disability Status Scale (EDSS) score after four years showed no change compared to baseline. No Relapses or MRI activity were noted during that period. Four years of Three Parameter No Evidence of Disease Activity (NEDA-3) was achieved by 90% of the per protocol population, which is defined as no relapses, no increase in disability (as measured by EDSS), and no new or active (enhancing) lesions on their MRI scans.

In the PPMS Phase II study, all participants received a 40mg dose of GA Depot once every four weeks. AEs were mainly mild. The most common AEs included injection site reactions and general weakness. No unexpected AEs were reported. EDSS score remained stable for all patients and no 12-week Confirmed Disability Progression (CDP) was detected. Mean Nine Hole Peg Test (9HPT) scores and Timed 25-Foot Walk (T25FW) remained stable.

Ehud Marom, Chairman and Chief Executive Officer of Mapi, said, “We are encouraged by the high four-year NEDA-3 score which we believe will position GA Depot among the leading MS treatments. The study provided evidence of the product’s long-term safety, tolerability, and efficacy in RRMS patients and offered very strong rationale for continued development.

“We are also pleased to report that we have now dosed more than 300 patients in our ongoing Phase 3 study for RRMS, which is designed to support a New Drug Application (NDA). Notwithstanding the impact that the COVID-19 pandemic has had on drug development timelines around the world, we remain on track



to complete this study as planned with no change to our original plan. Importantly, GA-based therapies are deemed safe by the Multiple Sclerosis International Federation (MSIF) to be dosed in a COVID-19 environment. We are very much looking forward to data from this Phase 3 study and continue to work closely with our commercialization partner Mylan to bring this significant therapeutic advancement to MS patients globally.”

Rajiv Malik, President of Mylan, commented, “Mylan is committed to meeting unmet needs through our collaboration with Mapi by leveraging our global platform and scientific and commercial expertise to advance new treatment options for patients living with MS. The results of Mapi’s RRMS Phase 2 study and continued progress on the recruitment for the ongoing Phase 3 study represent additional positive steps forward in our efforts to serve the MS patient community, which already includes the offering of a comprehensive MS portfolio of medicines such as glatiramer acetate 20 mg/mL and 40 mg/mL, and more recently dimethyl fumarate delayed release capsules. In parallel to the efficient, ongoing clinical development, we continue to advance commercial planning to bring GA Depot to market and look forward to expanding access for patients.”

The company welcomes attendees to meet with us virtually at MSVirtual2020 to learn more about:

1. **Abstract Number: #2107, Poster Number: LB1228**, Abstract Title: Glatiramer Acetate Depot (Extended-Release) Phase IIa Study in Patients with RRMS: Safety, Tolerability and Efficacy Four-Years Analysis.
2. **Abstract Number: #2106, Poster Number: LB1227**, Abstract Title: Glatiramer Acetate Depot (extended-release) Phase IIa study in patients with Primary Progressive Multiple Sclerosis: safety and efficacy snapshot.

#### **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. For more information, please visit: [www.mapi-pharma.com](http://www.mapi-pharma.com).

**Contacts:**

Alex Mogle  
Vice President, Corporate Development  
Mapi Pharma  
+972 52 6080297  
[alex@mapi-pharma.com](mailto:alex@mapi-pharma.com)

Bob Yedid  
Managing Director  
LifeSci Advisors, LLC  
646-597-6979  
[bob@LifeSciAdvisors.com](mailto:bob@LifeSciAdvisors.com)