Mapi Pharma Announces Positive Top-Line Results from GA Depot Phase III Trial for Relapsing forms of Multiple Sclerosis (RMS)

The study evaluating a long-acting glatiramer acetate injection, GA Depot 40 mg once every four weeks, met the primary endpoint, significantly reducing the annualized relapse rate (ARR) by 30.1 percent compared to placebo

NESS ZIONA, Israel – Sep. 21, 2022 – Mapi Pharma Ltd., a fully integrated, late-stage clinical development pharmaceutical company focused on introducing innovative long-acting depot injectable products, announced today positive top-line results from the GA Depot (a long acting glatiramer acetate) Phase III clinical trial assessing the efficacy, safety and tolerability of a once monthly GA Depot 40 mg compared to placebo in relapsing forms of multiple sclerosis (RMS) patients. Top-line efficacy results showed that GA Depot 40 mg meet the primary endpoint versus placebo in significantly reducing the ARR. The one-year multinational, multicenter, randomized, Phase III, double blind, parallel group, placebo-controlled study in subjects with relapsing forms of multiple sclerosis (RMS) to assess the efficacy, safety and tolerability of GA Depot, IM injection once monthly recruited 1,016 patients at 112 multinational sites.

Top Line Results Highlights

- The study met its primary endpoint showing that GA Depot 40 mg statistically significantly reduced the annualized relapse rate (ARR) by 30.1 percent compared to placebo (p=0.0066)

Analyses of various secondary efficacy endpoints and safety are ongoing. Following the initial 12-month placebo-controlled period, there is an ongoing one year open-label period extension of the trial.

“We are pleased with the topline results of this study that show the potential of GA Depot 40 mg to offer patients an effective treatment option using a more convenient dosing regimen which may potentially improve compliance and adherence,” said Ehud Marom, CEO and Chairman, Mapi Pharma, “We believe the positive results set us on a path to commercialize GA Depot and we will work with our partner Viatris to make this potentially valuable new treatment option available to patients with RMS as early as possible. We look forward to providing the other secondary endpoints and overall safety and tolerability of the drug in the near future.”

“The positive top-line efficacy results from the GA Depot 40 mg Phase III trial are an exciting step forward in our long-standing commitment to supporting the needs of the multiple sclerosis community. GA Depot has the potential to be complementary to our comprehensive MS portfolio,” said Rajiv Malik, President, Viatris. “We look forward to our continued partnership with Mapi to deliver on our strategy of providing access to more complex and novel products and our mission to empower people worldwide to live healthier at every stage of life.”

“In an international Phase 3 double-blind, randomized, placebo-controlled trial, once monthly intramuscular injections of depot glatiramer acetate (GA Depot) demonstrated statistically significant efficacy, comparable to other available formulations of GA, that supports its potential designation as a first line therapy for relapsing forms of multiple sclerosis. The monthly administration of GA Depot should offer patients a much more preferable schedule than current regimens of GA, a long-standing pillar in the

treatment of MS, and lead to improved patient satisfaction and medication adherence," 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.

Mapi Pharma and Viatris plan to work with regulatory authorities in the major markets to determine next steps.

About the Study

The multinational Phase III Study was designed to examine the safety, efficacy and tolerability of glatiramer acetate (GA) 40 mg intramuscular injection administered once every four weeks compared to placebo in a randomized double-blind placebo-controlled design in patients with relapsing forms of multiple sclerosis. The primary endpoint of the study is the total number of confirmed relapses during a 12-month, placebo-controlled phase. A total of 1,016 subjects were randomized into two groups, receiving either 40mg of GA Depot or placebo, via intramuscular injection (IM), once every 4 weeks for a total of 13 doses.

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). 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 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. 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 Viatris (NASDAQ: VTRS) for GA Depot in an agreement under which Viatris was granted an exclusive license to commercialize the GA Depot injection product for relapsing forms of multiple sclerosis. Mapi's portfolio also includes a leading development of Depot GLP-1 for diabetes, weight control, Parkinson's disease and potentially Alzheimer's disease with innovative IP. 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 and is manufacturing and marketing its own generic versions of Fingolimod (Gilenya®) and Apremilast (Otezla®) in specific markets. 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

Contacts:

Alex Mogle
Vice President, Corporate Development
Mapi Pharma
+972 52 6080297
alex@mapi-pharma.com

Bob Yedid
Managing Director
LifeSci Advisors, LLC
646-597-6979
bob@LifeSciAdvisors.com