Mapi Pharma Announces Presentation of Phase II Results of Glatiramer Acetate Depot at ECTRIMS-ACTRIMS 2017 Congress in Paris

Data Suggest that GA Depot Has Potential to Ease the Treatment Burden and Improve Patient Compliance in MS

Patients on GA Depot Achieved a No Evidence of Disease Activity (NEDA) Score of 84.6%

Phase III Trial Planned for 2018

NESS ZIONA, Israel – Oct. 31, 2017 – Mapi Pharma Ltd., a fully integrated, clinical stage biopharmaceutical company, presented the Phase II results of its lead product Glatiramer Acetate (GA/Copaxone®) Depot for the treatment of relapsing remitting multiple sclerosis (RRMS) as late breaking news at the ECTRIMS-ACTRIMS meeting in Paris.

The study is titled "A Prospective 1-year, Open-label, Two Arms, Multicenter, Phase II Study to Assess Safety, Tolerability and Efficacy of Once a Month Long-acting Intramuscular Injection of 80mg or 40mg Glatiramer Acetate (GA Depot) in Subjects with Relapsing Remitting Multiple Sclerosis (RRMS)"[1]. A total of 25 subjects previously treated for at least one year with Copaxone® were enrolled. GA Depot was injected every 4 weeks and has a linear release profile over approximately 30 days.

The primary endpoint is the safety and tolerability of the GA Depot. Secondary endpoints include the relapse rate during the study compared to the relapse rate observed in the 12 months prior to study entry during which these patients were treated with Copaxone®, changes from baseline to end of treatment on the number of enhancing lesions and new lesions on brain MRI scans, and the change from baseline to end of treatment of the Expanded Disability Status Scale (EDSS) score.

The study achieved the primary endpoint for safety and tolerability. The data suggests a good safety and tolerability profile for the 40mg dose, which was superior to the 80mg dose. Adverse events include injection site reactions, which were mainly mild and transient. The main injection site reactions reported were pain, induration, swelling and erythema. There were no systemic immediate post-injection reactions, as reported with Copaxone® use. For the (secondary) efficacy endpoints, the data suggests that the relapse rate during the study was comparable to the reported rate over the previous one-year period, during which patients were treated with Copaxone®, with one relapse recorded overall in the entire population during the trial compared with two relapses recorded in during the year prior to study entry. MRI scans did not show changes from baseline (no new T2 lesions and T1 gadolinium-enhancing lesions) for 92% of the per protocol population, and the mean EDSS score did not change in comparison to baseline mean EDSS score. Finally, there was an encouraging No Evidence of Disease Activity (NEDA) score of 84.6% for the per protocol population. NEDA is defined as the absence of all of the following: relapses, 12-week confirmed disability progression (CDP), as well as no new T2 lesions and T1 gadolinium-enhancing lesions during the study.

The patients that completed the one-year study asked to continue treatment with GA Depot and not with Copaxone®, which initiated the study extension.

The study was approved by the Israeli Ministry of Health and was conducted at eight clinical sites in Israel.

Prof. Aaron Miller, Professor of Neurology, Icahn School of Medicine at Mount Sinai Hospital, NY, and the Coordinating PI for Mapi's Phase III trial with GA Depot, said, "GA Depot offers a monthly injection versus the daily or thrice-weekly injections of glatiramer acetate sold in the market today. If the Phase III results replicate those of Phase II, GA Depot is expected to significantly improve the mode of treatment for patients with MS by significantly reducing the number of injections, easing the treatment burden and increasing patient compliance."

Ehud Marom, Chairman and CEO of Mapi said, "Following the capital raise we concluded in Q3 2017, we will be initiating the Phase III trial in 2018 and are currently looking for the best partner to commercialize our drug. GA Depot, if approved, will provide patients with an improved quality of treatment experience at a reduced burden, and has the potential to become a leading therapy for MS."

According to a recent survey published at seventh joint ECTRIMS-ACTRIMS meeting in Paris, nearly 1 million people in U.S. have MS, a neurodegenerative disorder of the central nervous system (The Multiple Sclerosis Foundation)[2].

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, as well as 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 an LCM version of Copaxone® (glatiramer acetate (GA) injection) which requires an injection daily or every other day. Mapi is built on strong chemical and pharmaceutical R&D capabilities as well as a deep understanding of the global market and of regulatory needs, together with the ability to foster local cooperation and enduring relationships in all of the countries in which it operates. Mapi is headquartered in Israel, with R&D facilities in Israel and China, and an API production facility in the Neot-Hovav Eco Industrial Park south of Beersheba, Israel. Mapi has a strong IP position, filing numerous patent applications for APIs and formulations. For more information, please visit: www.mapi-pharma.com

1. https://clinicaltrials.gov/ct2/show/NCT02212886?term=Mapi+Pharma&rank=1
2. https://msfocus.org/About-Us/MSF-News-Articles/89

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