



## **Mapi Pharma Presents Phase II Extension Results of Glatiramer Acetate Depot (GA Depot) at ECTRIMS 2018 in Berlin**

81.8% Patients on GA Depot Demonstrated No Evidence of Disease Activity (NEDA) at 2 years

GA Depot Has Potential to Address Multiple Sclerosis Treatment Burden and Improve Patient Compliance

**NESS ZIONA, Israel – Oct. 9<sup>th</sup>, 2018** – Mapi Pharma Ltd., a fully integrated, late-stage clinical development biopharmaceutical company will present two-year clinical data from its Phase II study of GA Depot for the treatment of relapsing remitting multiple sclerosis (RRMS) at the 34th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), which will take place on October 10-12 in Berlin, Germany. The results will be featured as part of Poster Session #3, on Friday, October 12<sup>th</sup>, 2018, between 12:15pm and 2:15pm CET and as an e-poster.

In the extension study, all participants received a 40mg dose of GA Depot once every 4 weeks. The number of adverse events (AEs) was considerably reduced during the second year of treatment compared with the first year. No immediate post-injection reactions, as are frequently seen with Copaxone<sup>®</sup> and generic glatiramer acetate, were detected. Efficacy results showed there was no significant change in mean Expanded Disability Status Scale (EDSS) score at two years compared with baseline in the per protocol population (PPP). No MRI disease activity was noted in any patients during that period. Eighty-one point eight percent (81.8%) of PPP patients achieved NEDA (No Evidence of Disease Activity) at two years.

Dr. Shlomo Flechter, Head of The MS Clinical Research and Therapy Unit at Assaf Harofeh Medical Center and the Coordinating Primary Investigator of the study extension commented, "These results suggest that GA Depot is safe, well tolerated and efficacious. The high proportion of patients in the per protocol population that achieved NEDA (84.6% and 81.8%, at one and two years, respectively) is particularly encouraging. If these results will be confirmed in the placebo-controlled Phase III study, GA Depot has the potential to establish a new standard of care for MS drugs."

Ehud Marom, Chairman and CEO of Mapi said, "The encouraging results of the GA Depot two-year study provide evidence of the product's safety, tolerability, and efficacy in RRMS patients. The results support our conviction that GA Depot can provide a meaningful therapeutic benefit to MS patients, with a significant reduction in injection frequency and increased adherence."

Mylan President Rajiv Malik added, "We are very pleased to achieve this important milestone with our partner, Mapi. The positive Phase II extension results across multiple measures reinforces our strong development program for GA Depot, and we look forward to progressing to a Phase III clinical trial. We're committed to developing new treatment options for the 2.3 million individuals living with MS worldwide."

### **About GA Depot**

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GA Depot consists of extended-release microspheres containing glatiramer acetate, intended for administration once every 28 days and has a linear release profile over that time period. Mapi Pharma has successfully completed an open-label Phase IIa clinical trial with GA Depot for RRMS, is carrying out Phase IIa for PPMS and is preparing to initiate a pivotal Phase III clinical trial to support marketing applications. GA Depot is being developed by Mapi Pharma in a strategic partnership with Mylan N.V. (NASDAQ: MYL).

### **About Mapi Pharma**

Mapi Pharma is a late 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. GA Depot is the most advanced product candidate in a series of depot long-acting injections in the company’s pipeline. Mapi is built on strong chemical and pharmaceutical R&D capabilities, deep understanding of the global market and of regulatory needs and its ability to foster local cooperation and enduring relationships in all of the countries in which it operates. Mapi is headquartered in Israel and has R&D and manufacturing facilities in Israel and China. Mapi maintains a strong IP position, filing numerous patent applications for APIs and formulations. For more information, please visit: [www.mapi-pharma.com](http://www.mapi-pharma.com)

### **About Mylan**

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at [investor.mylan.com](http://investor.mylan.com).



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