Mylan to Acquire the Global Marketing Rights to a Once-monthly Glatiramer Acetate Product through an Investment and Partnership with Israeli Company Mapi Pharma

April 10, 2018

Once approved, this product could represent a significant milestone for patients with relapsing-remitting multiple sclerosis

Mapi Pharma has completed an open-label Phase II clinical trial and is preparing to commence a pivotal Phase III clinical trial to support marketing applications

HERTFORDSHIRE, England and PITTSBURGH and NESS ZIONA, Israel, April 10, 2018 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL), one of the world's leading pharmaceutical companies, and Mapi Pharma Ltd., a fully integrated, clinical late stage biopharmaceutical company, today announced that the two companies will partner on the development and commercialization of GA Depot, a long-acting Glatiramer Acetate product. Mylan is acquiring global marketing rights to the product.

GA Depot is a proposed once-monthly injection for the treatment of patients with relapsing-remitting multiple sclerosis, or RRMS. Multiple sclerosis (MS) organizations have estimated that 2.3 million individuals are living with MS worldwide. In the U.S., preliminary results of an MS prevalence study by the National MS Society estimate that nearly 1 million people are living with MS. Relapsing-remitting MS accounts for approximately 85% of initial MS diagnoses.

Mylan President Rajiv Malikcommented: "Improving the lives of MS patients around the world is one of Mylan's primary goals. We recognize that medication convenience is very important to the MS community, and we believe that GA Depot, once approved, will provide an important and welcomed treatment option. GA Depot also will add to our already-strong portfolio of central nervous system products. We appreciate the opportunity to work with Mapi Pharma and its successful and proven founder, Ehud Marom, and we believe that our teams are well poised for a successful collaboration as we work through the remaining clinical and regulatory phases to bring this important product to market."

Mylan Chairman Robert J. Courycommented: "Over the past several years, I have observed firsthand the strength and resilience of Israel's business and scientific community as well as its strong workforce. The country's scientific research leadership is renowned worldwide, and Mylan's partnership and collaboration with Mapi Pharma represents the most recent example of our continued commitment to invest and maintain strong relationships in Israel. I am particularly grateful for Mapi Pharma CEO and Chairman Ehud Marom's leadership in this transaction. I look forward to the positive impact this MS product will have for patients worldwide."

Ehud Marom, CEO and Chairman of Mapi Pharma Ltd, commented, "As one of Israel's leading biotech companies, we are pleased and excited to have partnered and collaborated with Mylan in bringing this very important new product to the millions of MS patients around the globe. GA Depot is expected to significantly improve the mode of treatment for patients with MS by reducing the number of injections, easing the treatment burden and increasing patient compliance. We look forward to working with Mylan to bring this important drug to MS patients."

Mapi Pharma has strong research capabilities in the development of long-acting depot injections. Mylan brings to this collaboration its regulatory expertise, unique global commercial platform and significant experience in launching other Glatiramer Acetate injection products. The partnership is subject to approval by the Israeli Innovation Authority.

Mapi Pharma has completed a prospective one-year, open-label Phase II clinical trial. Mapi Pharma and Mylan are in the process of preparing to submit an investigational new drug application to the U.S. Food and Drug Administration, as well as other global health authorities, and to commence a pivotal Phase III clinical trial to support a new drug marketing application under the 505(b)(2) regulatory pathway.

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.

About MAPI Pharma

Mapi Pharma is a clinical stage pharmaceutical company, engaged in the development of high barrier to entry products that target large markets and generic drugs that include complex active pharmaceutical ingredients ("APIs") and formulations. GA Depot is the first 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. It has R&D facilities in Israel and China. Mapi has a strong IP position, filing numerous patent applications for APIs and formulations. For more information, please visit: www.mapi-pharma.com

Forward-Looking Statements: Mylan

This press release includes statements that constitute "forward-looking statements", including with regard to: the development and commercialization

of a once-monthly Glatiramer Acetate injection; that once approved, this product could represent a significant milestone for patients with relapsing-remitting multiple sclerosis; that Mapi Pharma has completed an open-label Phase II clinical trial and is preparing to commence a pivotal Phase III clinical trial to support marketing applications; that Mylan believes that GA Depot, once approved, will provide an important and welcomed treatment option; that GA Depot also will add to Mylan's already-strong portfolio of central nervous system products; that we believe that our teams are well poised for a successful collaboration as we work through the remaining clinical and regulatory phases to bring this important product to market; and that Mapi Pharma and Mylan are in the process of preparing to submit an investigational new drug application to the U.S. Food and Drug Administration, as well as other global health authorities, and to commence a pivotal Phase III clinical trial to support a new drug marketing application under the 505(b)(2) regulatory pathway. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: that the partnership is subject to approval by the Israeli Innovation Authority; success of clinical trials and our or our partners' ability to execute on new product opportunities; any regulatory, legal or other impediments to our or our partners' ability to bring products to market; other risks inherent in product development; the scope, timing, and outcome of any ongoing legal proceedings, including government investigations, and the impact of any such proceedings on our or our partners' businesses; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions; the effect of any changes in our or our partners' customer and supplier relationships and customer purchasing patterns; any other changes in third-party relationships; changes in the economic and financial conditions of the businesses of Mylan or its partners; uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

Mylan

Better Health for a Better World®

View original content with multimedia:http://www.prnewswire.com/news-releases/mylan-to-acquire-the-global-marketing-rights-to-a-once-monthly-glatiramer-acetate-product-through-an-investment-and-partnership-with-israeli-company-mapi-pharma-300626931.html

SOURCE Mylan N.V.

Christine Waller (Media), 724.514.1968 ; Melissa Trombetta (Investors), 724.514.1813