Viatris and Mapi Pharma Announce FDA Acceptance of New Drug Application Filing for GA Depot for the Treatment of Relapsing Forms of Multiple Sclerosis

August 7, 2023

FDA assigns PDUFA target action date of March 8, 2024

New Drug Application supported by positive Phase III efficacy and safety clinical trial results

Milestone builds upon Viatris' long-standing and continued commitment toward addressing the unmet needs of the MS community

PITTSBURGH and NESS ZIONA, Israel, Aug. 7, 2023 /PRNewswire/ -- Viatris Inc. (NASDAQ: VTRS), a global healthcare company, and Mapi Pharma Ltd., a fully integrated, late-stage clinical development pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the companies' recently submitted New Drug Application (NDA) for GA Depot 40 mg. The product is a long-acting glatiramer acetate being investigated as a once-monthly injection for the treatment of relapsing forms of multiple sclerosis (RMS). The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of March 8, 2024.

Viatris President Rajiv Malik said, "The NDA filing acceptance for GA Depot is yet another example of our continuous commitment to look for opportunities to enhance existing therapies and innovation to support unmet medical needs. Our application is backed by Phase III efficacy and safety data, and we believe, when approved, GA Depot could improve patient experience through fewer injections, greater tolerability and increased compliance. This milestone gives us further confidence in the strength of our GA Depot clinical program, and we look forward to continuing to work closely with FDA to bring access to this important complex medicine to patients."

According to a landmark study funded by the National Multiple Sclerosis Society, nearly one million people are living with MS in the U.S., which is more than twice as many people than was previously thought.[1] Approximately 85 percent of people with MS are initially diagnosed with relapsing-remitting multiple sclerosis.[2]

The GA Depot NDA filing is supported by results from a multinational, double blind, placebo-controlled Phase III clinical trial evaluating the efficacy, safety and tolerability of GA Depot compared with placebo in patients with RMS. 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. The study concluded that the product offers a preferable schedule and with expected fewer Injection Site Reactions than other GA products. The study met its primary endpoint showing that GA Depot 40 mg statistically significantly reduced the annualized relapse rate by 30.1 percent compared to placebo (p=0.0066).

"We are confident that GA Depot, when approved, will represent an important advancement in MS care by offering a convenient once-monthly option for patients which may potentially improve compliance and adherence, and the medicine is well positioned to deliver on this important unmet need," said Ehud Marom, CEO and Chairman, Mapi Pharma. "I commend the teams at Mapi and Viatris for the strong collaboration which has leveraged our collective expertise in complex products to deliver this novel medicine."

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).

References:

1. **https://www.nationalmssociety.org/What-is-MS/Who-Gets-MS/How-Many-People**
2. **https://www.nationalmssociety.org/What-is-MS/Types-of-MS/Relapsing-remitting-MS**

About Viatris
Viatris Inc. (NASDAQ: VTRS) is a global healthcare company empowering people worldwide to live healthier at every stage of life. We provide access to medicines, advance sustainable operations, develop innovative solutions and leverage our collective expertise to connect more people to more products and services through our one-of-a-kind Global Healthcare Gateway®. Formed in November 2020, Viatris brings together scientific, manufacturing and distribution expertise with proven regulatory, medical, and commercial capabilities to deliver high-quality medicines to patients in more than 165 countries and territories. Viatris' portfolio comprises more than 1,400 approved molecules across a wide range of therapeutic areas, spanning both non-communicable and infectious diseases, including globally recognized brands, complex generic and branded medicines, and a variety of over-the-counter consumer products. With more than 38,000 colleagues globally, Viatris is headquartered in the U.S., with global centers in Pittsburgh, Shanghai and Hyderabad, India. Learn more at viatris.com and investor.viatris.com, and connect with us on Twitter, LinkedIn, Instagram and YouTube.

About Mapi Pharma
Mapi Pharma 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. Mapi Pharma partnered with Viatris 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. The Company is also marketing its own generic versions of Fingolimod (Gilenya®) and Apremilast (Otezla®) in specific geographic markets. Mapi's portfolio also includes a leading development of Depot drugs for Schizophrenia, GLP-1 for diabetes, weight control, Parkinson's disease and potentially Alzheimer's with innovative intellectual property. 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, and an API production facility, and an aseptic manufacturing and a Fill & Finish facility for injectable Finished Dosage Forms, all in Israel. 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

This press release includes statements that constitute "forward-looking statements." These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward looking statements may include statements regarding FDA acceptance of NDA filing for GA Depot for the treatment of relapsing forms of multiple sclerosis; FDA assigns PDUFA target action date of March 8, 2024; the NDA filing acceptance for GA Depot is yet another example of our continuous commitment to look for opportunities to enhance existing therapies and innovation to support unmet medical needs; our application is backed by Phase III efficacy and safety data, and we believe, when approved, GA Depot could improve patient experience through fewer injections, greater tolerability and increased compliance; this milestone gives us further confidence in the strength of our GA Depot clinical program, and we look forward to continuing to work closely with FDA to bring access to this important complex medicine to patients. Factors that could cause or contribute to such differences include, but are not limited to: the possibility that the Company may be unable to realize the intended benefits of, or achieve the intended goals or outlooks with respect to, its strategic initiatives; the possibility that the Company may be unable to achieve expected benefits, synergies and operating efficiencies in connection with acquisitions, divestitures, or its global restructuring program, within the expected timeframe or at all; impairment charges or other losses related to the divestiture or sale of businesses or assets; the Company's failure to achieve expected or targeted future financial and operating performance and results; the potential impact of public health outbreaks, epidemics and pandemics, including the ongoing challenges and uncertainties posed by COVID-19; actions and decisions of healthcare and pharmaceutical regulators; changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; any regulatory, legal or other impediments to Viatris' ability to bring new products to market, including but not limited to "at-risk" launches; Viatris' or its partners' ability to develop, manufacture, and commercialize products; the scope, timing and outcome of any ongoing legal proceedings, and the impact of any such proceedings; any significant breach of data security or data privacy or disruptions to our information technology systems; risks associated with international operations; the ability to protect intellectual property and preserve intellectual property rights; changes in third-party relationships; the effect of any changes in Viatris' or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatris or its partners; uncertainties and matters beyond the control of management, including general economic conditions, inflation and exchange rates; failure to execute stock repurchases consistent with current expectations; stock price volatility; and the other risks described in Viatris' filings with the Securities and Exchange Commission (SEC). Viatris routinely uses its website as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC's Regulation Fair Disclosure (Reg FD). Viatris undertakes no obligation to update these statements for revisions or changes after the date of this release other than as required by law.

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