



## **Viatriis and Mapi Pharma Statement Regarding New Drug Application for GA Depot**

March 11, 2024

Viatriis Inc. has been informed that Mapi Pharma Ltd. has received a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for GA Depot 40 mg from the U.S. Food and Drug Administration (FDA). The Companies are reviewing the content of the CRL and will be determining the appropriate next steps. The Companies continue to believe in the potential of the product to provide an important new treatment advancement for patients with multiple sclerosis.

The receipt of this CRL does not result in a change to Viatriis' 2024 financial guidance or its new product revenue range of \$450-550M.

### Forward-Looking Statements

This statement 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 receipt of a CRL for the NDA for GA Depot 40 from the FDA; that the Companies will be determining the appropriate next steps; the Companies continuing to believe in the potential of the product to provide an important new treatment advancement for patients with multiple sclerosis; and that the receipt of this CRL does not result in a change to Viatriis' 2024 financial guidance or its new product revenue range of \$450-550M. Because forward-looking 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: 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 Viatriis' ability to bring new products to market, including but not limited to "at-risk" launches; Viatriis' 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; the possibility that Viatriis 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 Viatriis may be unable to achieve intended or expected benefits, goals, outlooks, synergies, growth opportunities and operating efficiencies in connection with divestitures, acquisitions, other transactions or restructuring programs, within the expected timeframes or at all; goodwill or impairment charges or other losses related to the divestiture or sale of businesses or assets; Viatriis' failure to achieve expected or targeted future financial and operating performance and results; the potential impact of public health outbreaks, epidemics and pandemics; 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 Viatriis' or its partners' customer and supplier relationships and customer purchasing patterns; the impacts of competition; changes in the economic and financial conditions of Viatriis 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 Viatriis' filings with the Securities and Exchange Commission (SEC). Viatriis 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). Viatriis undertakes no obligation to update these statements for revisions or changes after the date of this statement other than as required by law.