



## **Viatriis is First to Receive FDA Approval of Generic Restasis® (Cyclosporine Ophthalmic Emulsion 0.05%) to Treat Dry Eye Disease**

February 3, 2022

### **Approval Reinforces Viatriis' Steadfast Commitment to Breaking Down Barriers and Expanding Access to Complex Generic Products**

#### **Milestone Achieved After Decade-Long Investment in Product Development and Numerous Legal Victories The Company is Launching Immediately**

PITTSBURGH, Feb. 3, 2022 /PRNewswire/ -- [Viatriis Inc.](#) (NASDAQ: VTRS) today announced that its subsidiary, Mylan Pharmaceuticals Inc., has received approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Cyclosporine Ophthalmic Emulsion 0.05%, the first generic version of Allergan's Restasis®. There are no remaining legal or regulatory barriers, and the company is launching immediately.



Viatriis President [Rajiv Malik](#) said: "I am pleased that Viatriis has received the first FDA approval for generic Restasis after working for nearly a decade not only to develop a more affordable product but also to remove all barriers to entry and achieve patient access. We are also proud to add another first to our growing list of industry-setting scientific achievements in bringing to market complex and difficult-to-manufacture products."

Viatriis Developed Markets President Tony Mauro said: "The approval of generic Restasis reinforces our ongoing commitment to deliver innovative solutions and increase access to more affordable treatment options for patients. We look forward to quickly bringing this important product to millions of Americans with chronic dry eye disease."

Cyclosporine Ophthalmic Emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca, also known as dry eye. Dry eye disease is a common condition that occurs when a patient's tears are unable to provide adequate lubrication for their eyes. Tears can be inadequate and unstable for many reasons, but the instability can lead to discomfort, inflammation and potential damage of the eye's surface.


#### **About Viatriis**

[Viatriis Inc.](#) (NASDAQ: VTRS) is a new kind of 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, Viatriis 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. Viatriis' 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, a growing portfolio of biosimilars, and a variety of over-the-counter consumer products. With a global workforce of approximately 38,000, Viatriis is headquartered in the U.S., with global centers in Pittsburgh, Pennsylvania, Shanghai, China, and Hyderabad, India. Learn more at [viatriis.com](#) and [investor.viatriis.com](#), and connect with us on Twitter at [@ViatriisInc](#), [LinkedIn](#) and [YouTube](#).

#### **Forward-Looking Statement**

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 about Viatriis receiving FDA approval of Cyclosporine Ophthalmic Emulsion 0.05%, the first generic version of Allergan's Restasis®; that the approval reinforces Viatriis' steadfast commitment to breaking down barriers and expanding access to complex generic products; that there are no remaining legal or regulatory barriers, and the company is launching immediately. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to: the potential impact of public health outbreaks, epidemics and pandemics, including the ongoing challenges and uncertainties posed by the COVID-19 pandemic; the integration of Mylan N.V. and Pfizer Inc.'s Upjohn business (the "Upjohn Business"), which combined to form

Viatriis (the "Combination") and the implementation of our global restructuring initiatives being more difficult, time consuming or costly than expected, or being unsuccessful; the ability to achieve expected benefits, synergies, and operating efficiencies in connection with the Combination or its restructuring initiatives within the expected timeframe or at all; 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; any significant breach of data security or data privacy or disruptions to our information technology systems; risks associated with international operations, including our operations in China; 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; and the other risks 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 release other than as required by law.

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