



Viatriis Inc. Announces Receipt of the First FDA Approval for Generic Version of Symbicort® Inhalation Aerosol, Breyna™ (Budesonide and Formoterol Fumarate Dihydrate Inhalation Aerosol), in Partnership with Kindeva

March 16, 2022

Approval continues track record of successful firsts in developing complex generic medicines to help increase patient access

PITTSBURGH and ST. PAUL, Minn., March 16, 2022 /PRNewswire/ -- [Viatriis Inc.](#) (NASDAQ: VTRS) and [Kindeva Drug Delivery L.P.](#) today announced that, Mylan Pharmaceuticals Inc., a Viatriis subsidiary, has received approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Breyna™ (Budesonide and Formoterol Fumarate Dihydrate Inhalation Aerosol), the first approved generic version of AstraZeneca's Symbicort®. Breyna, a drug-device combination product, is indicated for certain patients with asthma or chronic obstructive pulmonary disease (COPD) and will be available in 160 mcg/4.5 mcg and 80 mcg/4.5 mcg dosage strengths.

Viatriis CEO [Michael Goettler](#) commented: "The FDA final approval of Breyna, the first FDA-approved generic version of Symbicort, is an exciting milestone both for our company and the many patients living with asthma and COPD. Our success with this partnership and approval is yet another proof point of the impact of our Global Healthcare Gateway® which enables us to join with Kindeva to provide patients in need with new options."

Viatriis President [Rajiv Malik](#) added: "The momentous FDA final approval of Breyna is further evidence of our well-established development expertise and proven ability to move up the value chain with more complex products by leveraging our robust scientific capabilities to target gaps in healthcare and patient needs. This approval also builds on our past successes of bringing other complex product firsts to market and demonstrates the continued delivery of our strong pipeline."

This approval presents an opportunity for Viatriis to launch Breyna in 2022 as the upcoming court proceedings develop. In December 2021, the U.S. Court of Appeals for the Federal Circuit reversed the infringement judgment against Viatriis and ordered the case remanded back to the U.S. District Court for the Northern District of West Virginia for further proceedings.

Aaron Mann, CEO of Kindeva Drug Delivery, added: "We are pleased that Viatriis has received full FDA approval for this important respiratory product. This important milestone is reflective of our sustained commitment to inhalation and complex drug delivery, from technical formulation, clinical program management, and regulatory submission, and I'm grateful to my many Kindeva colleagues for their contributions."

The full indication for Breyna includes asthma in patients six years of age and older; and the maintenance treatment of airflow obstruction and reducing exacerbations for patients with COPD, including chronic bronchitis and/or emphysema. COPD is a term used to describe chronic lung diseases and is characterized by breathlessness; it affects more than 16 million Americans. Asthma causes swelling of the airways resulting in difficulty breathing, and approximately 25 million Americans have the chronic condition.

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 portfolio of biosimilars, and a variety of over-the-counter consumer products. With a global workforce of approximately 37,000, 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](#).

About Kindeva Drug Delivery

Headquartered in Woodbury, Minnesota, Kindeva Drug Delivery is a leading global contract development and manufacturing organization (CDMO) in the pharmaceutical industry, with major R&D and manufacturing sites in the UK at Loughborough and Clitheroe. Kindeva provides unique technologies and quality services to its customers, ranging from formulation and product development to commercial manufacturing. Kindeva focuses on complex drug programs, and its current offering spans inhalation drug delivery, transdermal drug delivery, microneedle transdermal systems, and connected drug delivery. Kindeva employs approximately 1,000 people worldwide. [www.kindevadd.com](#).

Forward-Looking Statement: Viatriis

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 receipt of the first FDA approval for generic version of Symbicort® inhalation aerosol, Breyna, in partnership with Kindeva; the FDA final approval is an exciting milestone both for Viatriis and the many patients living with asthma and COPD; our success with this partnership and approval is yet another proof point of the impact of our Global Healthcare Gateway® which enables us to join with Kindeva to provide patients in need with new options; the momentous FDA final approval of Breyna is further evidence of our well-established development expertise and proven ability to move up the value

chain with more complex products by leveraging our robust scientific capabilities to target gaps in healthcare and patient needs; this approval builds on our past successes of bringing other complex product firsts to market and demonstrates the continued delivery of our strong pipeline; this approval presents an opportunity for Viatris to launch Breyna in 2022 as the upcoming court proceedings develop; and the outcome of ongoing litigation. 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 pending transaction between Viatris and Biocon Biologics Limited, pursuant to which Viatris will contribute its biosimilar products and programs to Biocon Biologics in exchange for cash consideration and a convertible preferred equity interest in Biocon Biologics, may not achieve its intended benefits; the integration of Mylan N.V. and Pfizer Inc.'s Upjohn business (the "Upjohn Business"), which combined to form Viatris (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 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; 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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