Viatris Inc. and Kindeva Drug Delivery Announce FDA Tentative Approval of the First Abbreviated New Drug Application Generic Version of Symbicort® (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol

March 8, 2021

Milestone reinforces Viatris' commitment to complex products and innovative solutions to help increase patient access

PITTSBURGH and ST. PAUL, Minn., March 8, 2021 /PRNewswire/ -- Viatris Inc. (NASDAQ: VTRS) and Kindeva Drug Delivery L.P. today announced that the U.S. Food and Drug Administration (FDA) granted tentative approval of budesonide/formoterol fumarate dihydrate products, the first generic version of Symbicort® based on an Abbreviated New Drug Application (ANDA). Symbicort is indicated for certain patients with asthma or chronic obstructive pulmonary disease (COPD).

Viatris CEO Michael Goettler commented: "The FDA's tentative approval of generic Symbicort represents yet another significant milestone for Viatris in advancing access to treatment for respiratory patients. It also further demonstrates our deep commitment to continuing to leverage our scientific and regulatory expertise for a wide range of noncommunicable and infectious diseases. Our success with this partnership and approval underscores how Viatris intends to execute and optimize our Global Healthcare Gateway® as a Partner of Choice ™for companies such as Kindeva to expand access to medicines for patients worldwide."

Viatris President Rajiv Malik added: "I am very proud of this important regulatory milestone as it once again demonstrates our strong scientific and regulatory teams' continued success. This only further enhances our confidence that through the Global Healthcare Gateway® and partnerships, like this one with Kindeva, we will continue to build and commercially launch robust branded and complex generic portfolios."

The FDA provided tentative approval at this time due to ongoing patent litigation. On March 2, 2021, the U.S. District Court for the Northern District of West Virginia found that the asserted claims of AstraZeneca's Symbicort patents, U.S. Patent Nos. 7,759,328, 8,143,239, and 8,575,137, are not invalid for obviousness. Viatris and Kindeva disagree with the district court decision. While the trial court decision prevents commercial launch at this time, the companies intend to file an appeal to continue vigorously defending their position that the patents are invalid. Viatris and Kindeva are committed to bringing a generic Symbicort to market as soon as possible.

"This FDA tentative approval reflects the strength of the partnership between Viatris and Kindeva, and further demonstrates Kindeva's industry-leading capabilities in formulation, development, and manufacturing of complex combination products," said Aaron Mann, CEO of Kindeva Drug Delivery. "Once final FDA approval is achieved, Kindeva looks forward to providing Viatris with reliable, quality supply from our state-of-the-art commercial filling and packaging lines in our Northridge, California facility."

Viatris has not planned any revenue for 2021 from generic Symbicort, and the product's potential launch revenue was not included in the company's recently announced 2021 financial guidance.

Symbicort had U.S. branded sales of $3.5 billion for the 12 months ending January 2021, according to IQVIA.

About Viatris

Viatris 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 through the combination of Mylan and Pfizer's Upjohn business, 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, a growing portfolio of biosimilars and a variety of over-the-counter consumer products. With a global workforce of approximately 45,000, 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 at @ViatrisInc, LinkedIn and YouTube.

About Kindeva Drug Delivery
Headquartered in St. Paul, Minnesota, Kindeva Drug Delivery is a leading global contract development and manufacturing organization (CDMO) in the pharmaceutical industry. 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, microstructured transdermal systems (microsystems), and connected drug delivery. Kindeva employs over 1,000 people worldwide. For more information, visit www.kindevadd.com.

Forward-Looking Statements: Viatris
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 the FDA's tentative approval of budesonide/formoterol fumarate dihydrate products, the first generic version of Symbicort® based on an ANDA; that this further demonstrates Viatris deep commitment to continuing to leverage our scientific and regulatory expertise for a wide range of non-communicable and infectious diseases; the success with this partnership and approval underscores how Viatris intends to execute and optimize its Global Healthcare Gateway® as a Partner of Choice ™for companies such as Kindeva to expand access to medicines for patients worldwide; that this only further enhances Viatris' confidence that through the Global Healthcare Gateway® and partnerships, like this one with Kindeva, we will continue to build and commercially launch robust branded and complex generic portfolios; statements about ongoing patent litigation; that while the trial court decision prevents commercial launch at this time, the companies intend to file an appeal to continue vigorously defending their position that the patents are invalid; that Viatris and Kindeva are committed to bringing a generic Symbicort to market as soon as possible; that once final FDA approval is achieved, Kindeva looks forward to providing Viatris with reliable, quality supply from their state-of-the-art commercial filling and packaging lines in our Northridge, California facility; and that Viatris has not planned any revenue for 2021 from generic Symbicort, and the product's potential launch revenue was not included in the company's recently announced 2021 financial guidance. 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 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, 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 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 Viatris' filings with the Securities and Exchange Commission. 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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