Viatris Wins Court Decision Invalidating AstraZeneca's Symbicort® Patent

November 10, 2022

PITTSBURGH, Nov. 10, 2022 /PRNewswire/ -- Viatris Inc. (NASDAQ: VTRS), a global healthcare company, today announced that it and Kindeva Drug Delivery L.P. have won a significant court decision in which the U.S. District Court for the Northern District of West Virginia found that AstraZeneca's Symbicort® patent, U.S. Patent No. 10,166,247, is invalid. The district court determined that the patent is invalid on two separate grounds – lack of written description and lack of enablement.

Viatris President Rajiv Malik said: "We are extremely pleased with the court's decision as it clears away yet another of AstraZeneca's invalid patents, which have only served to block generic versions and delay access to this important product for American patients. This affirms Viatris' continuing efforts to break down barriers to patient access for important medicines. We already have FDA approval for our generic Symbicort product, and we look forward to the opportunity to bring our more affordable product to market."

Today's decision marks the fourth Symbicort® patent to be found either not infringed or invalid. In May, after Viatris and Kindeva won an appeal, AstraZeneca stipulated that the Company's budesonide/formoterol fumarate dihydrate products would not infringe U.S. Patent Nos. 7,759,328, 8,143,239, and 8,575,137.

Viatris and Kindeva previously announced that Mylan Pharmaceuticals Inc., a Viatris subsidiary, 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.

AstraZeneca recently filed a new complaint asserting infringement of a fifth Symbicort® patent, which issued April 26, 2022, and shares the same specification and named inventors as the '247, '328, '239 and '137 patents. A trial on U.S. Patent No. 11,311,558 is currently scheduled for December 13, 2022. The '558 patent expires on January 29, 2023, with pediatric exclusivity expiring on July 29, 2023.

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 about the decision by the U.S. District Court for the Northern District of West Virginia that AstraZeneca's Symbicort® patent, U.S. Patent No. 10,166,247, is invalid; Viatris looking forward to the opportunity to bring its more affordable product to market; 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; that 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.

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, a portfolio of biosimilars and a variety of over-the-counter consumer products. With approximately 37,000 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 at @ViatrisInc, LinkedIn and YouTube.

About Kindeva Drug Delivery

Headquartered in Woodbury, Minnesota, Kindeva Drug Delivery is a leading global contract, research, development and manufacturing organization (CRDMO) in the pharmaceutical industry, with additional R&D sites in Union City, California and Loughborough, UK as well as major manufacturing sites in Northridge, California, Loughborough, UK and Clitheroe, UK. 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, including metered-dose and dry power inhalers as well as nebulizer delivery, transdermal drug delivery, intradermal drug delivery, and connected drug delivery. Kindeva employs approximately 1,000 people worldwide. Learn more at www.kindevadd.com and connect with us on LinkedIn.

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