Viatris Announces Launch of Breyna™ (budesonide and formoterol fumarate dihydrate) Inhalation Aerosol, the First FDA-Approved Generic Version of Symbicort® for People with Asthma and Chronic Obstructive Pulmonary Disease, in Partnership with Kindeva

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Launch demonstrates companies' commitment to bringing complex generic medicines to the market to help increase patient access

PITTSBURGH and WOODBURY, Minn., July 31, 2023 /PRNewswire/ -- Viatris Inc. (NASDAQ: VTRS), a global healthcare company, and Kindeva Drug Delivery L.P. today announced the launch of Breyna™ (budesonide and formoterol fumarate dihydrate) Inhalation Aerosol, the first generic version of AstraZeneca's Symbicort® with an Abbreviated New Drug Application (ANDA) approved by the U.S. Food and Drug Administration (FDA). Breyna, a drug-device combination product, is indicated for certain patients with asthma or chronic obstructive pulmonary disease (COPD) and will be immediately available in both 80 mcg/4.5 mcg and 160 mcg/4.5 mcg dosage strengths.



Viatris Head of North America Jose Cotarelo said: "We are excited to bring Breyna to the U.S. market for the many Americans living with asthma and COPD. This launch represents years of hard work breaking down barriers to access and builds upon our past successes of bringing other complex products to market as we continue to move up the value chain. Being the first to bring an FDA-approved generic version of Symbicort to patients is a true example of how access is the cornerstone of our mission to empower people worldwide to live healthier at every stage of life."

The indications for Breyna include asthma in patients six years of age and older, and the maintenance treatment of airflow obstruction and reducing exacerbations in patients with COPD, including chronic bronchitis and/or emphysema. Breyna is not indicated for the relief of acute bronchospasm. The 160 mcg/4.5 mcg is the only strength indicated for the treatment of COPD. COPD is a term used to describe a certain kind of chronic lung disease 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.

Milton Boyer, CEO of Kindeva Drug Delivery, added: "The launch of Breyna represents a significant milestone as it is the first FDA-approved generic version of Symbicort in the U.S., one of the most prescribed complex drug-device combination products to treat asthma and COPD. We are pleased for Viatris as well as the many Kindeva colleagues who have worked tirelessly to leverage our complex drug-delivery expertise for this important respiratory product — supporting a persistent need to continue bringing more quality medicines for asthma and COPD to patients."

To further expand access to Breyna, Viatris has established a copay program offered for eligible commercially-insured patients, which may help reduce out-of-pocket expenses on prescriptions to as little as $20 per 30-day supply. The program offers $30/month or up to $360 per year with 12 refills annually. The program will be available in August.

About Breyna
Breyna is indicated for the treatment of asthma in patients 6 years and older not adequately controlled on a long-term asthma-control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta2-adrenergic agonists (LABA). Breyna 160 mcg/4.5 mcg dosage is indicated for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, and Breyna 160 mcg/4.5 mcg is also indicated to reduce exacerbations of COPD. Breyna is NOT indicated for the relief of acute bronchospasm.

Important Safety Information
Breyna is contraindicated in the primary treatment of status asthmaticus or other acute episode of asthma or COPD where intensive measures are required, and in hypersensitivity to any of the ingredients in Breyna. Use of long-acting beta2-adrenergic agonists (LABA) as monotherapy (without inhaled corticosteroids [ICS]) for asthma is associated with an increased risk of asthma-related death. Available data from controlled clinial trials also suggest that use of LABA as monotherapy increases the risk of asthma-related hospitalization in pediatric and adolescent patients. These findings are considered a class effect of LABA. When LABA are used in fixed dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared to ICS alone. Breyna is NOT a rescue medication and does NOT replace fast-acting inhalers to treat acute symptoms. Breyna should not be initiated in patients during rapidly deteriorating episodes of asthma or COPD. Patients who are receiving Breyna should not use additional formoterol or other LABA for any reason. Localized infections of the mouth and pharynx with Candida albicans has occurred in patients treated with Breyna. Patients should rinse the mouth after inhalation of Breyna. Lower respiratory tract infections, including pneumonia, have been reported following the administration of ICS. Due to possible immunosuppression, potential worsening of infections could occur. A more serious or even fatal course of chickenpox or measles can occur in susceptible patients. It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression may occur, particularly at higher doses. Particular care is needed for patients who are transferred from systemically active corticosteroids to ICS. Deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available ICS. Caution should be exercised when considering administration of Breyna in patients on long-term ketoconazole and other known potent CYP3A4 inhibitors. As with other inhaled medications, paradoxical bronchospasm may occur with Breyna. Immediate hypersensitivity reactions may occur, as demonstrated by cases of urticaria, angioedema, rash, and bronchospasm. Excessive beta-adrenergic stimulation has been associated with central nervous system and cardiovascular effects. Breyna should be used with caution in patients with cardiovascular disorders especially coronary insufficiency, cardiac arrhythmias, and hypertension. Long-term use of ICS may result in a decrease in bone mineral density (BMD Assessment of BMD is recommended prior to initiating Breyna and periodically thereafter. ICS may result in a reduction in growth velocity when administered to pediatric patients. Glaucoma, increased intracolular pressure, and cataracts have been reported following the administration of ICS, including budesonide, a component of Breyna. Close monitoring for glaucoma and cataracts is warranted in patients with a change in vision or history of increased intraocular pressure. In rare cases, patients on ICS may present with systemic eosinophilic conditions. Breyna should be used with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines. The most common adverse reactions ≥3% reported in asthma clinical trials included nasopharyngitis, headache, upper respiratory tract infection, pharyngolaryngeal pain, sinusitis, influenza, back pain, nasal congestion, stomach discomfort, vomiting, and oral candidiasis. The most common adverse reactions ≥3% reported in COPD clinical trials included nasopharyngitis, oral candidiasis, bronchitis, sinusitis, and upper respiratory tract infection. Breyna should be administered with caution to patients being treated with MAO inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents. Beta-blockers may not only block the pulmonary effect of beta-agonists, such as formoterol, but may produce severe bronchospasm in patients with asthma. ECG changes and/or hypokalemia associated with nonpotassium-sparing diuretics may worsen with concomitant beta-agonists. Use caution with the coadministration of Breyna.

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, and a variety of over-the-counter consumer products. With more than 38,000 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
Kindeva Drug Delivery is a global contract development manufacturing organization focused on drug-device combination products. Kindeva Drug Delivery develops and manufactures products across a broad range of complex drug-delivery formats, including injectables (autoinjector, intradermal, microneedle), pulmonary & nasal, and transdermal patches. Its service offering spans early-stage feasibility through commercial scale drug product fill-finish, container closure system manufacturing, and drug-device product assembly. Kindeva Drug Delivery serves a global client base from its nine manufacturing and research and development facilities located in the U.S. and U.K. For more information, please visit www.kindevadd.com.

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 that the launch of Breyna demonstrates the companies' commitment to bringing complex generic medicines to the market to help increase patient access; Breyna will be immediately available in both 80 mcg/4.5 mcg and 160 mcg/4.5 mcg dosage strengths; this launch represents years of hard work breaking down barriers to access and builds upon our past successes of bringing other complex products to market as we continue to move up the value chain; to further expand access to Breyna, Viatris has established a copay program offered for eligible commercially-insured patients, which may help reduce out-of-pocket expenses on prescriptions to as little as $20 per 30-day supply; and, the program will be available in August. Factors that could cause or contribute to such differences include, but are not limited to: the possibility that the Company 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 the Company may be unable to achieve expected benefits, synergies and operating efficiencies in connection with acquisitions, divestitures, or its global restructuring program, within the expected

timeframe or at all; impairment charges or other losses related to the divestiture or sale of businesses or assets; the Company's failure to achieve expected or targeted future financial and operating performance and results; the potential impact of public health outbreaks, epidemics and pandemics, including the ongoing challenges and uncertainties posed by COVID-19; 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, 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 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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