Viatris Inc. Announces FDA Tentative Approval of a Pediatric Formulation of Dolutegravir (DTG) Under PEPFAR

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Tentative approval will help enhance access to WHO-recommended pediatric medicine and reduce the cost of HIV treatment for children in low- and middle-income countries

PITTSBURGH, Nov. 23, 2020 /PRNewswire/ -- Viatris Inc. (NASDAQ: VTRS), a new kind of healthcare company, today announced tentative approval from the U.S. Food and Drug Administration (FDA) for a New Drug Application for pediatric dolutegravir tablets for oral suspension, 10 mg. The new formulation is a result of a collaboration with ViiV Healthcare, the Clinton Health Access Initiative and Unitaid to help expand access to children living with HIV/AIDS in low- and middle-income countries. Tentative approval was granted under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) which permits products that are not approved for marketing in the U.S. because of patent protection or other marketing restrictions to be distributed in other countries where they are critically needed.

Pediatric dolutegravir tablets were approved for use in combination with other antiretroviral (ARV) agents for the treatment of HIV-1 infection in pediatric patients at least 4 weeks old and weighing at least 3 kg. The World Health Organization (WHO) recommends this product as part of a preferred first-line treatment regimen for children who meet the criteria. According to the organization, half of HIV-positive infants will die before their second birthday without prompt diagnosis and treatment.

Viatris President Rajiv Malik said, "The FDA's decision clears the way for Viatris to deliver this urgently needed treatment to some of the world's most vulnerable children living in regions that are home to 99% of children living with HIV. Pediatric dolutegravir tablets are a significant new addition to a product portfolio that has made Viatris the world's largest supplier of ARVs. We have a deep commitment to increasing access to more affordable treatments and will continue to find innovative solutions to reach those in need."

Dolutegravir tablets for oral suspension should not be co-administered with dofetilide; it may cause hypersensitivity reactions; hepatotoxicity has been reported in patients receiving dolutegravir-containing regiments and embryo-fetal toxicity may occur when used at the time of conception and in early pregnancy.

Viatris, launched last week through the combination of Mylan N.V. and Pfizer's Upjohn business, provides approximately 40% of those on treatment for HIV/AIDS with a Viatris product, including approximately 60% of the world's HIV-positive children on treatment.

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.

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements," including with regard to Viatris™ announcing FDA tentative approval of a pediatric formulation of DTG under PEPFAR, that tentative approval will help enhance access to WHO-recommended pediatric medicine and reduce the cost of HIV treatment for children in low- and middle-income countries; and statements about the transaction pursuant to which Mylan N.V. combined with Pfizer Inc.'s Upjohn business (the "Combination") to form Viatris. These statements are made pursuant to the safe harbor

provisions of the Private Securities Litigation Reform Act of 1995. 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 and the Upjohn Business being more difficult, time consuming or costly than expected; the ability to achieve expected benefits, synergies and operating efficiencies in connection with the Combination within the expected timeframe or at all or to successfully integrate Mylan and the Upjohn Business; 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; 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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