Mylan Pharmaceuticals ULC Launches Wixela® Inhub® (fluticasone propionate and salmeterol inhalation powder, USP), the First Available Bioequivalent Alternative to ADVAIR® DISKUS® (fluticasone propionate and salmeterol inhalation powder) in Canada

March 10, 2020

HERTFORDSHIRE, England and PITTSBURGH, March 10, 2020 /CNW/ -- Mylan Pharmaceuticals ULC today announced the launch of Wixela Inhub (fluticasone propionate and salmeterol inhalation powder, USP), the first available bioequivalent alternative to ADVAIR DISKUS in Canada. Wixela Inhub was approved by Health Canada in January for the twice daily maintenance treatment of asthma in patients age 4 and older not adequately controlled on long-term asthma control medications or whose disease warrants initiation of treatment with both inhaled corticosteroids and long-acting beta$_2$-agonists; or maintenance treatment of COPD.

Wixela Inhub is available in the 100 mcg/50 mcg, 250 mcg/50 mcg and 500 mcg/50 mcg strengths for asthma patients and the 250 mcg/50 mcg and 500 mcg/50 mcg strengths for COPD patients.

Mylan Canada Country Manager David Simpson commented: "We're pleased to offer Wixela Inhub as the first available bioequivalent alternative to ADVAIR DISKUS, one of the leading treatments for asthma and COPD management today. Wixela Inhub is the result of a $700M investment worldwide, including an extensive research and development program. With today's launch in Canada, we are pleased to expand access to this important medicine by providing a more affordable alternative to appropriate asthma and COPD patients."

The research and development program for Wixela Inhub compared all strengths of treatment to ADVAIR DISKUS in order to meet regulatory requirements of therapeutic equivalence for a substitutable generic. In the 28-day, randomized, double-blind, placebo-controlled, parallel group study of 1,122 adult asthma patients conducted to evaluate the local (lung) bioequivalence of Wixela Inhub 100 mcg/50 mcg and ADVAIR DISKUS 100 mcg/50 mcg, the two treatments produced equivalent efficacy. Both treatments were safe and well-tolerated with lower numbers of withdrawals due to asthma compared to the placebo group. The study included both naive and current users of ADVAIR DISKUS.

ADVAIR DISKUS had Canadian sales of $113.9 million for the 12 months ending December 31, 2019, according to IQVIA.

About Mylan
Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of approximately 7,500 marketed products around the world, including antiretroviral therapies on which approximately 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

Forward-Looking Statements
This press release includes statements that constitute "forward-looking statements," including with regard to the outcome of product launches. Factors that could cause or contribute to such differences include, but are not limited to any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

SOURCE Mylan N.V.