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Mylan's generic version of ADVAIR DISKUS for asthma, COPD patients gets FDA approval

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Mylan's Wixela Inhub will be 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 strength for COPD patients.

Mylan has announced the U.S. Food and Drug Administration approval of Wixela Inhub (fluticasone propionate and salmeterol inhalation powder, USP), the first generic of ADVAIR DISKUS.

Wixela Inhub will launch in the second half of February incorporating the latest safety information required by FDA earlier this month, which prompted an amendment to the label for certain inhaled corticosteroids, including ADVAIR DISKUS and any generic versions. Wixela Inhub will be 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 strength for COPD patients.

Mylan CEO Heather Bresch commented, "Mylan remains steadfast in its efforts to expand patient access to medicines, and the FDA approval of Wixela Inhub reinforces our commitment to provide patients greater choice and lower-cost alternatives. This milestone represents the culmination of an extensive research and development program and Mylan's more than $700 million of investment. We're proud of our Wixela Inhub team, who worked tirelessly and in close collaboration with the FDA to bring this important medicine to market and add it to our growing global portfolio of more than 700 respiratory products. As one of the leading providers of prescription medicines in the U.S., we continue to execute on our mission and do our part to reduce costs for patients and identify pathways that help increase sustainability for the U.S. healthcare system overall."

Wixela Inhub is indicated for the twice daily 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 agonists; maintenance treatment of COPD; and the reduction of COPD exacerbations in patients with a history of exacerbations. It is not indicated for the relief of acute bronchospasm.

Mylan President Rajiv Malik added, "We're pleased to offer the first FDA-approved generic of ADVAIR DISKUS, one of the

leading treatments for asthma and COPD management today. We've long been confident in the science around this product and are proud of the dedication of our scientific teams to bring Wixela Inhub to market. This complex product required a rigorous research and development program spanning over a decade and close collaboration with FDA to define the regulatory pathway. We also are proud to manufacture Wixela Inhub in our own state-of-the-art plant. This approval reinforces our ongoing commitment to increase access to more affordable treatment options for patients."

The research and development program for Wixela Inhub compared all strengths of treatment to ADVAIR DISKUS in order to meet the FDA requirements of therapeutic equivalence for a substitutable generic. In the 28-day, randomized, double-blind, placebo-controlled, parallel group study of 1,128 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.

"Patients enrolled in clinical trials found Wixela Inhub easy-to-use and highly effective at controlling their asthma in a clinical bioequivalence study. Asthma and respiratory specialists and primary care providers welcome this generic alternative to benefit many patients with asthma and COPD. We have waited for years for generic inhalers to emerge in respiratory medicine," said Edward Kerwin, MD of Crisor LLC, a division of the Clinical Research Institute located in Medford, Ore. and a Clinical Investigator on the Wixela Inhub clinical program.

ADVAIR DISKUS had U.S. sales of $4.2 billion for the 12 months ending November 30, 2018, according to IQVIA.