



Mylan Presents Equivalence and Device Usability Data on Wixela™ Inhub™ Compared to Advair Diskus® at American Thoracic Society International Conference

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Four posters highlight Mylan's rigorous research and development program

HERTFORDSHIRE, England, and PITTSBURGH, May 18, 2019 /PRNewswire/ -- Global pharmaceutical company [Mylan N.V.](#) (NASDAQ: MYL) today announced four scientific abstracts from the Wixela™ Inhub™ (fluticasone propionate and salmeterol inhalation powder, USP) development program that will be presented at the 2019 American Thoracic Society (ATS) International Conference in Dallas, May 17 – May 22. The data, available for the first time publicly, further supports the U.S. Food and Drug Administration's approval in January 2019 of Mylan's Abbreviated New Drug Application for Wixela Inhub, which is indicated for certain patients with asthma or chronic obstructive pulmonary disease (COPD).

Mylan President [Rajiv Malik](#) commented, "We are extremely proud to present for the first time publicly our rigorous data package that demonstrated therapeutic equivalence between Wixela Inhub and Advair Diskus®. The four studies being presented describe the pulmonary and systemic bioequivalence between the two products, device usability that enabled substitutability, and product and device robustness. The American Thoracic Society International Conference is the perfect forum to share with this important medical community the strong science that supported the introduction of the first FDA-approved therapeutically equivalent, substitutable generic of Advair Diskus®."

Mylan's data will be presented during the following poster sessions at the meeting.

- **Abstract 11902: Pulmonary Therapeutic Bioequivalence of Wixela™ Inhub™ and Advair Diskus® in Adults With Asthma**
 - May 19, 11:15 a.m. to 1 p.m. CT
 - Poster Session A64 - Clinical Asthma: Assessment and Treatment
 - Poster #786
- **Abstract 12321: Usability and Robustness of the Wixela™ Inhub™ Dry Powder Inhaler**
 - May 19, 11:15 a.m. to 1 p.m. CT
 - Thematic Poster Session A64 - Clinical Asthma: Assessment and Treatment
 - Poster #787
- **Abstract 8715: Wixela™ Inhub™ Dry Powder Inhaler: In Vitro Performance Compared with Advair Diskus® and Inhalation Profiles in Patients with Asthma or Chronic Obstructive Pulmonary Disease**
 - May 19, 11:15 a.m. to 1 p.m. CT
 - Thematic Poster Session A64 - Clinical Asthma: Assessment and Treatment
 - Poster #788
- **Abstract 12048: Equivalent Systemic Exposure to Fluticasone Propionate/Salmeterol Following Single Inhaled Doses of Advair Diskus® and Wixela™ Inhub™: Results of 3 Pharmacokinetic Equivalence Studies**
 - May 19, 11:15 a.m. to 1 p.m. CT
 - Thematic Poster Session A64 - Clinical Asthma: Assessment and Treatment
 - Poster #789

Full session details for the 2019 Scientific Sessions can be found at ATS website at conference.thoracic.org.

About Wixela Inhub

Wixela Inhub is indicated for the twice-daily treatment of asthma in patients age 4 and older not adequately controlled on long-term asthma 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. 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 strength for COPD patients.

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 more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 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 approximately 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.



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SOURCE Mylan N.V.

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