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ASIA EDITION

Teva announces FDA approval of first and only digital inhaler

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This is the first and only digital inhaler with built-in sensors which connects to a companion mobile application and provides inhaler use information to people with asthma and COPD.

Teva Pharmaceutical Industries Limited has announced that the U.S. Food and Drug Administration has approved ProAir Digihaler (albuterol sulfate 117 mcg) inhalation powder, the first and only digital inhaler with built-in sensors which connects to a companion mobile application and provides inhaler use information to people with asthma and COPD. ProAir Digihaler is indicated for the treatment or prevention of bronchospasm in patients aged four years and older with reversible obstructive airway disease, and for prevention of exercise-induced bronchospasm (EIB) in patients aged four years and older.

“This approval marks a significant milestone not only for Teva, but for the respiratory community as it allows patients and their caregivers to better understand inhaler usage through digital technology,” said Sven Dethlefs, Executive Vice President, Global Marketing & Portfolio. “Teva recognizes the importance of integrating technology into patient care, and we are very proud to lead the way with the approval of ProAir Digihaler. The digital technology built into ProAir Digihaler provides patients with data on their inhaler use, which may help them to have a more informed dialogue with their healthcare provider regarding their asthma or COPD management.”

ProAir Digihaler contains built-in sensors that detect when the inhaler is used and measure inspiratory flow. This inhaler-use data is then sent to the companion mobile app using Bluetooth Wireless Technology so patients can review their data over time, and if desired, share it with their healthcare professionals.

“There are 25 million Americans living with asthma, many of whom use inhalers as part of their treatment regimen. Despite advancements in care over the years, we know that many are using their rescue medications incorrectly or too often,” said Tonya Winders, President & CEO of the Allergy & Asthma Network. “The FDA approval of ProAir Digihaler is significant because it may help patients track their inhaler usage and provide data that can be used to work more closely with their HCPs on their asthma management. This approval is a major step forward and is indicative of how medications are evolving through technological innovations.”

The approval of ProAir Digihaler is based on the review of a supplemental new drug application (sNDA) submitted by Teva to the FDA. ProAir Digihaler combines a breath-activated, multi-dose dry powder inhaler with albuterol, the most widely used asthma rescue medication, with a built-in electronic module and a companion mobile app.

“One of the challenges physicians are faced with in caring for their asthma and COPD patients is knowing if their patients are

using their inhaled medication as they should. That's what makes a product like this so important to doctor-patient discussions," said Tushar Shah, M.D., Global Head of Specialty Clinical Development & Medical Affairs at Teva Pharmaceuticals. "Offering a tool that enables doctors to see data on their patients' inhaler usage will allow them to have more productive conversations about identifying issues and how to manage their illness."

ProAir Digihaler will be available in 2019 through a small number of "Early Experience" Programs, which will be conducted in partnership with healthcare systems and in limited geographies, in order to gather real-world experience. A national launch is planned for 2020.