

FDA nod for Teva's asthma inhaler

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Teva Pharmaceutical has announced that the US Food and Drug Administration (US FDA) has approved ProAir RespiClick (albuterol sulfate) inhalation powder. It is a breath-actuated, multi-dose, dry-powder, short-acting beta-agonist (SABA) inhaler for the treatment or prevention of bronchospasm in patients 12 years of age and older with reversible obstructive airway disease; and for the prevention of exercise-induced bronchospasm (EIB) in patients 12 years of age and older.

It is expected to become commercially available to patients during the second quarter of 2015.

"ProAir RespiClick is the first and only breath-actuated, dry-powder rescue inhaler to be approved by the FDA for the treatment of acute asthma symptoms," said Dr David I Bernstein of the University of Cincinnati College of Medicine, Division of Immunology, Allergy and Rheumatology. He added, "The approval of ProAir RespiClick is significant as it eliminates the need for hand-breath coordination during inhalation."

The approval was based on a comprehensive clinical development program consisting of eight clinical trials designed to evaluate the safety and efficacy of ProAir RespiClick in adults and adolescents (12 years of age and older) with asthma and EIB.

Clinical trial results has showed that ProAir RespiClick was both safe and effective with adverse events consistent with those seen with previous albuterol inhalers. The most common adverse events in greater than one percent of patients treated with ProAir RespiClick, compared to placebo, were back pain, body aches and pains, upset stomach, sinus headache, and urinary tract infection.

"Teva is committed to optimizing respiratory therapies through the development of new delivery systems that address needs

in the marketplace. The approval of ProAir RespiClick is an important step forward in the progress of Teva's respiratory portfolio as it represents the first U.S. approval of our core, breath-actuated, dry-powder delivery device platform which we believe will bring additional benefit to patients," said Mr Tushar Shah, senior vice-president, Teva Global Respiratory Research and Development.