QVAR® Redihaler™ (beclomethasone dipropionate HFA) – New formulation approval

- On August 7, 2017, Teva announced the FDA approval of QVAR Redihaler (beclomethasone dipropionate HFA) for the maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older.
    - QVAR Redihaler is not indicated for the relief of acute bronchospasm.
- QVAR Redihaler delivers the same active drug ingredient, beclomethasone diproprionate, as QVAR® inhalation aerosol. QVAR Redihaler uses a breath-actuated metered-dose inhaler, eliminating the need for hand-breath coordination during inhalation.
    - QVAR inhalation aerosol will be discontinued upon the launch of QVAR Redihaler.
- The efficacy and safety of QVAR Redihaler were demonstrated in 2 placebo-controlled studies in 695 patients 12 years of age and older and 1 placebo-controlled study in 568 patients 4 – 11 years of age. The primary endpoint for all 3 studies was the standardized baseline-adjusted trough morning forced expiratory volume in 1 second (FEV_1) area under the effect curve.
    - In the first study, patients in both treatment groups had significantly greater improvements in trough FEV_1 vs. placebo (80 mcg/day, least square (LS) mean change of 0.124 L [95% CI: 0.054, 0.193], 160 mcg/day, LS mean change of 0.116 L [95% CI: 0.048, 0.185]).
    - In the second study, patients in both treatment groups had significantly greater improvements in trough FEV_1 vs. placebo (320 mcg/day, LS mean change of 0.144 L [95% CI: 0.0807, 0.2066], 640 mcg/day, LS mean change of 0.150 L [95% CI: 0.0868, 0.2132]). Treatment with QVAR inhalation aerosol was similar to QVAR Redihaler (LS mean change of 0.148 L [95% CI: 0.0847, 0.2114]).
    - In the pediatric study, the primary endpoint was not statistically significant. However, change in weekly average of daily morning peak expiratory flow (L/min) was 11.3 [95% CI: 5.58, 17.06] and 8.5 [95% CI: 2.71, 14.24] for the 80 mcg/day and 160 mcg/day doses, respectively, at nominal significance.
- QVAR Redihaler is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required and in patients with hypersensitivity to any of the ingredients of QVAR Redihaler.
- Warnings and precautions of QVAR Redihaler include local effects, deterioration of asthma and acute episodes, transferring patients from systemic corticosteroid therapy, immunosuppression, paradoxical bronchospasm, immediate hypersensitivity reactions, hypercorticism and adrenal suppression, effects on growth, reduction in bone mineral density, and eye disorders.
- The most common adverse reactions (≥ 3% and > placebo) with QVAR Redihaler use were oral candidiasis, upper respiratory tract infection, nasopharyngitis, allergic rhinitis, oropharyngeal pain and sinusitis.
- The recommended starting dosage of QVAR Redihaler is based on previous asthma therapy and disease severity, including consideration of the patients' current control of asthma symptoms and risk of future exacerbation.
    - The recommended starting dosage for patients 12 years of age and older who are not on an inhaled corticosteroid is 40 mcg to 80 mcg twice daily, approximately 12 hours apart.

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  - The maximum recommended dosage for patients 12 years of age and older is 320 mcg twice daily.
  - The recommended starting dosage for patients aged 4 -- 11 years of age is 40 mcg twice daily, approximately 12 hours apart.
  - The maximum recommended dosage for patients 4 -- 11 years of age is 80 mcg twice daily.
  - QVAR Redihaler does not require priming.
  - QVAR Redihaler does not require shaking prior to use. Do not shake the inhaler with the cap open to avoid possible actuation of the device.
  - QVAR Redihaler should not be used with a spacer or volume holding chamber.

- Teva plans to launch QVAR Redihaler during the first quarter of 2018. QVAR Redihaler will be available as an 120-inhalation, pressurized, breath-actuated, metered-dose aerosol with a dose counter in two strengths: 40 mcg and 80 mcg.