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PART OF THE NOVARTIS COPD PORTFOLIO

Open up to a LAMA option in COPD

IMPROVED PATIENTS' QUALITY OF LIFE

(LS mean change in SGRQ total score vs. placebo, -3.32; $p<0.001$)[1,2†]

ONCE-DAILY Pr SEEBRI® BREEZHALER®

DEMONSTRATED 5-MINUTE ONSET AND 24-HOUR BRONCHODILATION

- FEV_1 improvement shown 5 minutes after first dose (0.093 L vs. placebo, $p<0.001$, serial spirometry)[1,3‡]
- Significantly greater LS mean FEV_1 vs. placebo demonstrated at all time points over 24 hours (LS mean FEV_1 [L] vs. placebo after first dose, $p<0.001$; time points were 5 min, 15 min, 30 min, 1 hr, 2 hrs, 3 hrs, 4 hrs, 6 hrs, 8 hrs, 10 hrs, 12 hrs, 23 hrs 15 min, 23 hrs 45 min)[4§]

Indication & clinical use:

SEEBRI® BREEZHALER® is indicated as a long-term once-daily maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

- Not indicated for the relief of an acute deterioration of COPD
- Can be used at the recommended dose in elderly patients 65 years of age and older
- Should not be used in patients under 18 years of age

Relevant warnings and precautions:

- Not indicated for treatment of acute episodes of bronchospasm
- Not indicated for treatment of acutely deteriorating COPD
- Worsening of narrow-angle glaucoma
- Worsening of urinary retention
- In severe renal impairment, use only if the expected benefit outweighs the potential risk
- Paradoxical bronchospasm

For more information:

Please consult the Product Monograph at www.novartis.ca/asknovartispharma/download.htm?res=seebri%20breezhaler_scrip_e.pdf&resTitleId=665 for important information relating to adverse events, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling the Medical Information Department at 1-800-363-8883.

LAMA: long-acting muscarinic antagonist; COPD: chronic obstructive pulmonary disease; LS: least square; SGRQ: St. George's Respiratory Questionnaire, measures health-related quality of life in symptoms, activities and impact on daily life[5]; FEV_1: forced expiratory volume in 1 second.

† GLOW2: A 52-week, randomized, double-blind, placebo-controlled parallel-group study of 1,060 patients with COPD. Patients received either SEEBRI® BREEZHALER® (glycopyrronium 50 mcg o.d.; n=525), placebo (n=268), or open-label tiotropium (18 mcg o.d.; n=267) as an active control. Primary endpoint was 24-hour post-dose (trough) FEV_1 following 12 weeks of treatment.

‡ GLOW1: A 26-week, randomized, double-blind, placebo-controlled parallel-group study to assess the efficacy, safety and tolerability of once-daily SEEBRI® BREEZHALER® (50 mcg) in patients with COPD (n=550); placebo (n=267).

§ LS mean FEV_1 (L) after first dose; SEEBRI® BREEZHALER® (n=169) vs. placebo (n=83), respectively: 5 min: 1.39 vs. 1.30; 15 min: 1.43 vs. 1.28; 30 min: 1.44 vs. 1.28; 1 hr: 1.47 vs. 1.28; 2 hrs: 1.53 vs. 1.34; 3 hrs: 1.53 vs. 1.35; 4 hrs: 1.52 vs. 1.35; 6 hrs: 1.48 vs. 1.33; 8 hrs: 1.47 vs. 1.33; 10 hrs: 1.47 vs. 1.32; 12 hrs: 1.45 vs. 1.31; 23 hrs 15 min: 1.37 vs. 1.27; 23 hrs 45 min: 1.39 vs. 1.31; $p<0.001$ for all time points.

References: 1. SEEBRI® BREEZHALER® Product Monograph. Novartis Pharmaceuticals Canada Inc., December 3, 2013. **2.** Kerwin E, Hébert J, Gallagher N *et al.* Efficacy and safety of NVA237 versus placebo and tiotropium in patients with COPD: the GLOW2 study. *Eur Respir J* 2012;40:1106-14. **3.** D'Urzo A, Ferguson GT, van Noord JA *et al.* Efficacy and safety of once-daily NVA237 in patients with moderate-to-severe COPD: the GLOW1 trial. *Respir Res* 2011;12(156):1-13. **4.** Data on file. Novartis Pharmaceuticals Canada Inc. **5.** Jones P. St. George's Respiratory Questionnaire Manual. Available from: www.healthstatus.sgul.ac.uk/SGRQ_download/SGRQ%20Manual%20June%202009.pdf. Accessed May 16, 2014.

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