QVA149 and glycopyrronium abstracts to be presented at ERS 2013

Tokyo, Japan – 4 September 2013: Sosei confirms the information released by Novartis that new data from the Novartis COPD respiratory portfolio are to be presented at the European Respiratory Society (ERS) Annual Congress 2013 in Barcelona, Spain (7-11 September).

Data include the latest pooled analyses from the Phase III IGNITE clinical trial program on Ultibro® Breezhaler® (QVA149 - indacaterol 85 mcg/glycopyrronium 43 mcg delivered dose, equivalent to 110 mcg/50 mcg metered dose per capsule)[1,2,3].

New exacerbation, lung function and safety data will also be presented on Seebri® Breezhaler® (glycopyrronium 44 mcg delivered dose equivalent to 50 mcg metered dose per capsule)[4,5], which, together with indacaterol maleate, is one of the monotherapy components of QVA149.

ERS is the largest respiratory meeting in the world, with delegates attending from more than 100 countries. All abstracts and details on timings can be accessed through the ERS website:
https://www.ersnetsecure.org/public/prg_congres.entree?ww_i_congres=135

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About QVA149

QVA149 is a once-daily investigational fixed dose combination of a long-acting beta$_2$-adrenergic agonist (LABA) and a long-acting muscarinic antagonist (LAMA), that received a positive opinion for approval from the European Medicine Agency's (EMA) Committee for the Human use of Medicinal Products (CHMP) in July 2013 as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. QVA149 also gained endorsement for approval in August from the Drug Committee of MHLW (Ministry of Health, Labour and Welfare) for the treatment of COPD in Japan.

About Seebri® Breezhaler®

Once-daily Seebri® Breezhaler® (glycopyrronium bromide) is a novel inhaled long-acting muscarinic antagonist (LAMA; also referred to as a long-acting anticholinergic) indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD[6]. Glycopyrronium bromide was exclusively licensed to Novartis in April 2005 by Sosei and its co-development partner Vectura. Seebri® Breezhaler® is approved in the EU/EEA, Japan (under brand name Seebri® Inhalation Capsules), Switzerland, Canada, Australia and a number of other countries.

References

1. Vogelmeier C *et al.* Once-daily QVA149 provides clinically meaningful improvements in lung function and clinical outcomes. [ERS abstract 851178; Session 82; Date: September 8, 2013 Time: 12:50-14:40].
2. Banerji D et al. Dual bronchodilation with once-daily QVA149 improves dyspnea and health status and reduces symptoms and rescue medication use in patients with COPD: the IGNITE trials. [ERS abstract 851388; Session 346; Date: September 10 2013 Time: 8:30-10:30]
3. Banerji D et al. Dual bronchodilation with once-daily QVA149 improves lung function and reduces exacerbations in patients with COPD: the IGNITE trials. [ERS abstract 851415; Session 346; Date: September 10 2013 Time: 8:30-10:30]
4. Wedzicha JA *et al.* Once-daily glycopyrronium improves lung function and reduces exacerbations in severe-to-very severe COPD patients: the SPARK study. [ERS abstract 851270; Session 41; Date: September 8, 2013 Time: 8:30-10:30].
5. Decramer M *et al.* Safety of once-daily glycopyrronium in patients with severe-to-very severe COPD: the SPARK study. [ERS abstract 851279; Session 346; Date September 10, 2013 Time: 8:30-10:30].
6. EMA. 2012. Seebri Breezhaler EU Summary of Product Characteristics. [Online] 17 October 2012. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002430/WC500133769.pdf. [Accessed 2 August 2013].