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ASIA EDITION

Novartis bronchodilator gets EU nod for COPD therapy

27 September 2013 | Regulatory | By BioSpectrum Bureau

Singapore: Novartis received European Commission approval for once-daily Ultibro Breezhaler (indacaterol 85 mcg/glycopyrronium 43 mcg) as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

In addition, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved once-daily Ultibro Inhalation Capsules (glycopyrronium 50 mcg / indacaterol 110 mcg), delivered through the Breezhaler device, for relief of various symptoms due to airway obstruction in chronic obstructive pulmonary disease (COPD). Ultibro Breezhaler / Ultibro Inhalation Capsules were developed under the name QVA149.

Dual bronchodilation with QVA149 is expected to set a new standard of care in COPD by combining the proven efficacy benefits and safety profiles of two established Novartis COPD treatments: the LABA, Onbrez Breezhaler (indacaterol); and the LAMA, Seebri Breezhaler (glycopyrronium bromide). Both these components are delivered through the Breezhaler device, as is QVA149, and are widely available around the world.

Dr David Epstein, division head, Novartis Pharmaceuticals, "We are very pleased that the European Commission and Japan approved QVA149, nearly simultaneously, for COPD patients. This rapid approval in Japan reflects our build-up of clinical trial and regulatory capabilities in Japan. Many COPD patients will now have a better treatment option, including first-line therapy with the launch of Ultibro Breezhaler in Europe."

Mr Timothy Wright, global head development, Novartis Pharmaceuticals, said that, "Since 2007, Novartis has received approvals for 15 new treatments and 16 new indications for existing treatments in Japan, Japan plays a critical role in our global clinical research program. In the last five years, Novartis has conducted 175 clinical studies in Japan with over 14,000 patients."