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Novartis's Ultibro Breezhaler receives EC, Japanese nod

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Singapore: Novartis has announced that the European Commission has approved 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, Labor 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.

"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," said Mr David Epstein, division head, Novartis Pharmaceuticals. "Many COPD patients will now have a better treatment option, including first-line therapy with the launch of Ultibro Breezhaler in Europe," Mr Epstein added.

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.

The approvals of QVA149 in Europe and Japan were based on the comprehensive IGNITE phase III clinical trial program, one of the largest international trial programs in COPD comprising 11 studies in total with more than 10,000 patients from 52 countries.