BioSpectrum the business of Bio & Health Sciences ASIA EDITION

AstraZeneca's Bevespi Aerosphere approved in the EU

03 January 2019 | News

Bevespi Aerosphere is a twice-daily, fixed-dose dual bronchodilator combining glycopyrronium, a long-acting muscarinic antagonist (LAMA), and formoterol fumarate, a long-acting beta2-agonist (LABA)

AstraZeneca has announced that the European Commission (EC) has approved Bevespi Aerosphere (glycopyrronium/formoterol fumarate) in a pressurised metered-dose inhaler (pMDI) as a maintenance dual bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Bevespi Aerosphere is the first medicine in its class to be approved by the EC in a pMDI. The approval offers patients with COPD an important new choice of inhaler device.

Dr Colin Reisner, Head of Respiratory, Global Medicines Development, said: "Bevespi Aerosphere is already available to COPD patients in the US and other countries, and this approval means we can now bring this new medicine to patients in Europe. Bevespi Aerosphere is the first dual-bronchodilator treatment delivered in our next-generation pressurised metered-dose inhaler using Aerosphere Delivery Technology."

Dr Omar Usmani, Consultant Physician in Respiratory Medicine at the National Heart & Lung Institute, Imperial College London and Royal Brompton Hospital, UK, said: "Bevespi Aerosphere is an important treatment option in COPD, particularly for patients with limited lung function and advanced age who may benefit from using a pMDI. The efficacy and safety profile of Bevespi Aerosphere has been well established in the Phase III PINNACLE programme."

Bevespi Aerosphere is a twice-daily, fixed-dose dual bronchodilator combining glycopyrronium, a long-acting muscarinic antagonist (LAMA), and formoterol fumarate, a long-acting beta2-agonist (LABA). The EC approval is based on the Phase III PINNACLE trial programme which evaluated the efficacy and safety of Bevespi Aerosphere and involved more than 5,000 patients with moderate to very-severe COPD.

Bevespi Aerosphere is also approved in the US, Canada, Australia, Turkey and Taiwan as a dual bronchodilator for the long-term maintenance treatment of COPD.

COPD is a progressive disease which can cause obstruction of airflow in the lungs resulting in debilitating bouts of breathlessness. It affects an estimated 384 million people worldwide and is predicted to be the third leading cause of death by 2020. Improving lung function, reducing exacerbations and managing daily symptoms such as breathlessness are important treatment goals in the management of COPD.

PINNACLE 1/2/4 were randomised, double-blinded, multi-centre, placebo-controlled trials conducted over 24 weeks, which compared the efficacy and safety of Bevespi Aerosphere administered twice daily via a pMDI, compared to its monotherapy components (glycopyrronium and formoterol fumarate) and to placebo.

In PINNACLE 1, open-label tiotropium was included as an active control. PINNACLE 3 was a multi-centre, randomised, double-blinded, parallel-group, chronic-dosing, active-controlled, 28-week safety extension trial of PINNACLE 1/2, which evaluated the long-term safety, tolerability, and efficacy of Bevespi Aerosphere administered twice daily via a pMDI compared to its monotherapy components. All the trials were conducted in patients with moderate to very-severe COPD.