

Novartis announces CLAIM study for COPD

23 February 2018 | News

Treatment with Novartis' Ultibro® Breezhaler® improved cardiac function in COPD patients with lung hyperinflation



Novartis has announced the publication of the CLAIM* study in the *Lancet Respiratory Medicine*, which demonstrated that treatment once-daily Ultibro® Breezhaler® (indacaterol/glycopyrronium 110/50 mcg) significantly improved lung and cardiac function, when compared to placebo, in chronic obstructive pulmonary disease (COPD) patients with lung hyperinflation.

Many people living with COPD are at increased risk of death and disability due to comorbid cardiovascular disease. Lung hyperinflation is common in people with COPD³, and has been linked to impaired cardiac function and a worsening of COPD symptoms, especially breathlessness⁴⁻⁶.

CLAIM is the first study to investigate the effects of dual bronchodilation on cardiac function and lung hyperinflation.

The CLAIM study met its primary endpoint demonstrating that treatment with Ultibro Breezhaler led to decreased lung hyperinflation and improvements in cardiac function after 14 days of treatment¹. This translated into clinically relevant patient benefits of improved health status and breathlessness (dyspnea), studied as exploratory endpoints.

The CLAIM study was a randomized, double-blinded, placebo-controlled, single-center, two period cross-over study comparing the effects of 14-day Ultibro® Breezhaler® therapy with placebo on cardiac and lung function in hyperinflated COPD patients¹.

It involved a total of 62 patients, of whom 57 completed both treatment periods¹. All patients had moderate-to-very severe COPD and confirmed lung hyperinflation (residual volume >135% predicted).

The primary endpoint of the study was to demonstrate the effect of 14-day once-daily Ultibro Breezhaler treatment on left ventricular end-diastolic volume (LV-EDV) as measured by MRI¹. Secondary endpoints included effects on lung function parameters as measured by residual volume (RVol), forced expiratory volume in one second (FEV₁) and forced vital capacity (FVC).

Cardiac assessments included right ventricular end-diastolic volume (RV-EDV), left and right ventricular stroke volume (LV-SV and RV-SV), left and right ventricular end-systolic volumes (LV-ESV and RV-ESV) and cardiac index (CI).

Shreeram Aradhya, Chief Medical Officer and Global Head of Medical Affairs for Novartis Pharmaceuticals said, "Lung hyperinflation is often associated with impaired cardiac function in patients with COPD. The publication of the CLAIM study is important for any COPD patient with signs of lung hyperinflation. For the first time, we demonstrated that treatment with

Ultibro Breezhaler can reduce lung hyperinflation and improve cardiac function, breathlessness and health status.”

In the CLAIM study Ultibro Breezhaler was well tolerated and its safety profile was comparable with placebo.