

Tiotropium in asthma* Media backgrounder

***Tiotropium is NOT APPROVED for use in asthma. The safety and efficacy of tiotropium have not yet been fully established in asthma.**

About tiotropium in asthma

- Tiotropium is an inhaled long-acting, anticholinergic bronchodilator. It works by opening narrowed airways and helping to keep them open for at least 24 hours^{1,2,3}
- Approved for the treatment of chronic obstructive pulmonary disease (COPD) for over ten years, tiotropium is the most prescribed maintenance COPD therapy worldwide. It is the first inhaled maintenance treatment to provide significant and sustained improvements in lung function in patients with COPD using once-daily dosing
- Phase III clinical trials of tiotropium Respimat® in asthma are being conducted to evaluate its efficacy and safety in patients who remain symptomatic despite inhaled corticosteroids (ICS) therapy (with long-acting beta2-agonist (LABA) or ICS alone)
 - In these studies, patients received tiotropium Respimat® in addition to their standard medication in an effort to more accurately represent clinical practice
- In the PrimoTinA-asthma® Phase III trials involving patients who remained symptomatic despite treatment with at least ICS/LABA (current standard treatment) it was observed that the addition of tiotropium Respimat® increased time to first severe asthma exacerbation, as well as time to first episode of asthma worsening, compared with standard treatment⁴
- In the Phase III MezzoTinA-asthma® studies it was observed that, in patients with symptomatic asthma despite moderate-dose maintenance ICS therapy, the addition of tiotropium Respimat® significantly improved lung function, provided sustained bronchodilation over 24 hours,⁵ and improved asthma control⁶

The unmet need for innovative treatments in asthma

- The goal of asthma therapy is to achieve and maintain clinical control which includes improving lung function, and reducing symptoms and exacerbation risk. This may be achieved by targeting underlying inflammation and airway obstruction
- Targeting inflammation is the cornerstone of treatment strategies for asthma and ICS are the most effective anti-inflammatory treatments
- The most commonly prescribed drug used in addition to ICS therapy is a LABA which has proven to be an effective treatment option in patients symptomatic on ICS alone

- ICS/LABA has become the current standard treatment for the majority of patients with asthma
- Despite current treatment options, in particular ICS/LABA, at least 40% of asthma patients still experience symptoms and could benefit from new treatment options^{7,8}

About the UniTinA-asthma® Phase III clinical trial programme

UniTinA-asthma®

- Comprehensive Phase III clinical trial programme designed to evaluate the efficacy and safety of tiotropium Respimat® in patients with asthma
- Includes a number of clinical studies investigating tiotropium Respimat® added to usual care in adults, adolescents and children (age 1+) with persistent asthma across the spectrum of asthma severities
- Current clinical trial programme consists of:
 - 11 studies
 - more than 4,000 patients
- Adult studies include:

PrimoTinA-asthma®:

Designed to assess tiotropium as add-on treatment for patients who are symptomatic on at least ICS/LABA therapy (current standard treatment)

MezzoTinA-asthma®:

Evaluating tiotropium as add-on treatment in patients who are symptomatic on moderate-dose maintenance ICS treatment

GraziaTinA-asthma®:

Assessing tiotropium as an add-on therapy in patients who are symptomatic on low-dose maintenance ICS treatment

About asthma

- Asthma is a chronic inflammatory disorder of the airways characterised by bronchoconstriction, mucus plugs, and increased inflammation when airways are exposed to risk factors such as allergens (including house dust mites, animals with fur, pollens and moulds), occupational irritants, tobacco smoke, viral respiratory infections, exercise or chemical irritants⁹
- Symptoms include recurring episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the early morning⁹
- An estimated 300 million people worldwide are affected by asthma⁹

Abstracts

European Respiratory Society Annual Congress 2013

Boehringer Ingelheim MezzoTinA-asthma® data

Abstract title: Tiotropium as add-on to inhaled corticosteroids significantly improves asthma control as reflected by the ACQ responder rate

Poster no.: P4130

Session: HALL 1-25, Asthma drugs: new findings, 12:50-14:40, Tuesday 10 September 2013

Abstract title: Tiotropium as add-on therapy to inhaled corticosteroids for patients with symptomatic asthma: Lung function and safety

Oral presentation: 4629

Session: Room 5.1 (CC5), LAMA, LABA, ICS and their combinations for the treatment of asthma and COPD, 14:45-16:45, Tuesday 10 September 2013

References

¹ Casaburi R, Mahler DA, Jones PW, *et al.* A long-term evaluation of once-daily inhaled tiotropium in chronic obstructive pulmonary disease. *Eur Respir J* 2002;19:217-224.

² Celli B, ZuWallack R, Wang S, *et al.* Improvement in resting inspiratory capacity and hyperinflation with tiotropium in COPD patients with increased static lung volumes. *Chest* 2003;124(5):1743-1748.

³ Casaburi R, Kukafka D, Cooper CB, *et al.* Improvement in exercise tolerance with the combination of tiotropium and pulmonary rehabilitation in patients with COPD. *Chest* 2005;127:809-817.

⁴ Kerstjens HAM, Engel M, Dahl R, *et al.* Tiotropium in asthma poorly controlled with standard combination therapy. *N Engl J Med* 2012;367:1198-1207.

⁵ Kerstjens HAM, Bleecker E, Meltzer E, *et al.* Tiotropium as add-on therapy to inhaled corticosteroids for patients with symptomatic asthma: lung function and safety. ERS 2013 abstract 853529.

⁶ Kerstjens HAM, Bleecker E, Meltzer E, *et al.* Tiotropium as add-on to inhaled corticosteroids significantly improves asthma control as reflected by the ACQ responder rate. ERS 2013 abstract 853658.

⁷ Bateman ED, Boushey HA, Bousquet J, *et al.* Can guideline-defined asthma control be achieved? The Gaining Optimal Asthma Control study. *Am J Respir Crit Care Med* 2004;170:836-844.

⁸ Partridge MR, Dal Negro RW, Olivieri D. Understanding patients with asthma and COPD: insights from a European study. *Prim Care Respir J* 2011;20(3):315-323.

⁹ Global Initiative for Asthma (GINA). Pocket Guide for Asthma Management and Prevention. Available at: <http://www.ginasthma.org/documents/1/Pocket-Guide-for-Asthma-Management-and-Prevention> [last accessed 16/07/13].