Boehringer Ingelheim enrols first patient in Phase III program for new once-daily fixed-dose combination of tiotropium plus olodaterol in COPD

Boehringer Ingelheim

Ingelheim, Germany, September 21, 2011 – Boehringer Ingelheim today announced enrolment has commenced in its TOviTO Phase III clinical trial program. It will investigate tiotropium plus olodaterol in a once-daily fixed-dose combination for the treatment of chronic obstructive pulmonary disease (COPD).

A progressive yet treatable disease that restricts patients' lives over time, COPD is estimated to affect over 210 million people worldwide and results in more deaths than breast cancer and diabetes combined. [1,2]

Tiotropium - marketed under the brand name Spiriva® in COPD – is a long-acting muscarinic antagonist (LAMA) that provides 24-hour bronchodilation by blocking M_3 muscarinic receptors. [3] Tiotropium is the most prescribed COPD drug worldwide with more than 34 million patient years. Olodaterol is a novel once-daily long-acting $ß_2$-agonist (LABA) that Boehringer Ingelheim has developed as an ideal partner to tiotropium in COPD.

Boehringer Ingelheim has decided to move the once-daily fixed-dose combination of tiotropium plus olodaterol into the TOviTO Phase III trial program on the back of promising olodaterol Phase III trial results, which will be published in the near future. The TOviTO program includes several trials that will provide important evidence to support olodaterol's potential to improve patients' lives beyond optimal bronchodilation. The first two trials to begin in the comprehensive TOviTO program will be TOnado 1 and its replicate study, TOnado 2. TOnado 1 & 2 will be the first two pivotal studies to evaluate the safety and efficacy of the fixed-dose combination for the treatment of COPD patients, and are planned to involve 5000 patients (2500 each) at more than 500 trial sites in approximately 40 countries.

The trials are multi-centered, multi-national, randomised, double-blind, parallel group studies that will compare the efficacy and safety of tiotropium plus olodaterol in fixed-dose combination with that of both mono-compounds (tiotropium and olodaterol). Both the fixed-dose combination and monotherapies will be administered once-daily, for 52 weeks, via Boehringer Ingelheim's Respimat® Soft Mist™ Inhaler (SMI). Respimat® SMI is a new generation inhaler that provides a unique slow moving and long-lasting soft mist [4,5] that is easy to inhale [6] and

produces superior lung deposition. [7,8] Respimat® SMI is preferred by patients compared to other currently available inhalers. [9,10,11]

Professor Roland Buhl, Head of the Pulmonary Department at the University of Mainz, Germany

Professor Roland Buhl, Head of the Pulmonary Department at the University of Mainz, Germany, and the Co-ordinating investigator for both trials, said: “We hypothesise the combination of tiotropium plus olodaterol, in a single Respimat® Inhaler device, will provide superior efficacy compared with the once-daily mono compounds. The addition of a LABA to tiotropium, a current COPD standard-of-care, could represent a significant advancement in COPD treatment. For the first time, patients would be able to receive their once-daily dose of tiotropium alongside a specifically selected LABA, all in the one, convenient inhaler.”

The trials’ primary endpoints will be bronchodilation – as measured by FEV_1[a] AUC_{0-3h}[b] response and trough FEV_1 response at 24 weeks - and health status (quality of life) – as measured by the Saint George’s Respiratory Questionnaire (SGRQ).

Professor Klaus Dugi, Corporate Senior Vice President Medicine, Boehringer Ingelheim

Professor Klaus Dugi, Corporate Senior Vice President Medicine, Boehringer Ingelheim, said: “Boehringer Ingelheim is committed to advancing respiratory research and treatment. The development of a true once-daily LABA as a partner to tiotropium underscores the company’s commitment to meet the unmet medical needs of COPD patients and improve clinical outcomes. Our goal is to provide patients with a LABA/LAMA fixed-dose combination in a device that was specifically designed with patient benefit and convenience in mind.”

[a]Forced Expiratory Volume in one second
[b]Area Under the Curve from 0 to 3 hours post-dose

About COPD
Chronic Obstructive Pulmonary Disease (COPD) is a major cause of death and disability throughout the world. Symptoms include cough, sputum (mucus or phlegm) production, and breathlessness on exertion. Acute worsening of these symptoms, i.e. exacerbations (sometimes referred to as COPD lung attacks due to their severe impact on patients' health) often occurs and can restrict a patient's ability to perform normal daily activities. [12] The latest World Health Organisation (WHO) figures estimate that more than 3 million people died from the disease in 2005. Dyspnoea (breathlessness), the main symptom of COPD, is characteristically persistent and progressive and has a serious impact on patients' quality of life. [12] At its most severe form, it even limits a patient performing simple tasks such as washing and dressing.

About Olodaterol
Olodaterol is a long acting β_2–agonist (LABA) in clinical development (Phase III) by Boehringer Ingelheim. It is being developed as an ideal partner to tiotropium. Phase III studies have confirmed olodaterol has a 24-hour duration of action and bronchodilator efficacy in patients with COPD when administered once-daily. Olodaterol as monotherapy showed promising results in Phase III that met the company's expectations and will be published in the near future.

About Tiotropium
Tiotropium (Spiriva®) is a long-acting inhaled anticholinergic medication and is the first inhaled treatment to provide significant and sustained improvements in lung function with once-daily dosing. Tiotropium positively impacts the clinical course of COPD, helping to change the way patients live with their disease [13,14] by opening narrowed airways and helping to keep them open for 24 hours. Tiotropium works through targeting a dominant reversible mechanism of COPD – cholinergic bronchoconstriction (closing of the airways) – and has demonstrated significant and sustained bronchodilation [15] (opening of the airways) and reduction in hyperinflation [16,17] (air trapping). Boehringer Ingelheim has marketed tiotropium as Spiriva® since 2002 (9 years).

About Respimat® Soft Mist™ Inhaler
Developed by Boehringer Ingelheim, Respimat® Soft Mist™ Inhaler (SMI) is a propellant-free, new generation inhaler with a unique delivery mechanism. It produces a long-lasting, slow moving Soft Mist™ [4,5] that is easy to inhale, easy to co-ordinate (forced inhalation is not required), reduces deposition in the mouth and throat and leads to superior lung deposition. [6,7,8] Therefore, Respimat® SMI is preferred by patients compared to other currently available inhalers. [9,10,11]

Boehringer Ingelheim: Leading respiratory forward
Treatment of COPD has been a major area of focus for Boehringer Ingelheim for decades and significant resources are dedicated to research in this field. More

recently, the Company has also branched out into developing treatment options for other airway diseases, including asthma, lung cancer, idiopathic pulmonary fibrosis and other respiratory indications. Boehringer Ingelheim's respiratory portfolio covers a wide range of treatment options and includes Spiriva® (tiotropium), Berodual® (fenoterol/ipratropium bromide), Berotec® (fenoterol), Combivent® (ipratropium bromide/salbutamol) and Atrovent® (ipratropium bromide).

Boehringer Ingelheim
The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 145 Operating Units (OPUs) and more than 42,000 employees. Since it was founded in 1885, the family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

As a central element of its culture, Boehringer Ingelheim is committed to socially responsible programs. Involvement in social projects, caring for employees and their families, and providing equal opportunities for all employees form the foundation of the global operations. Mutual cooperation and respect, as well as environmental protection and sustainability are intrinsic factors in all of Boehringer Ingelheim's endeavours.

In 2010, Boehringer Ingelheim posted net sales of about 12.6 billion euro while spending almost 24% of net sales in its largest business segment Prescription Medicines on research and development.

SOURCE [1]

Source URL (retrieved on *09/19/2014 - 12:43am*):
http://www.chem.info/news/2011/09/boehringer-ingelheim-enrols-first-patient-phase-iii-program-new-once-daily-fixed-dose-combination-tiotropium-plus-olodaterol-copd

Links:
[1] http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2011/21_september_2011olodaterol.html