Roche provides update on two identical phase III studies of lebrikizumab in people with severe asthma

- One study met its primary endpoint, showing lebrikizumab significantly reduced exacerbations in people with severe asthma; the second study did not meet this primary endpoint
- Roche continues to evaluate these study data to better understand the results
- Clinical studies in asthma, COPD, atopic dermatitis and idiopathic pulmonary fibrosis are ongoing

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced top-line results from two phase III studies. The LAVOLTA I-II studies were identical, double-blind, randomised, multicentre, placebo-controlled studies that evaluated the efficacy and safety of lebrikizumab in people with severe asthma.1,2

LAVOLTA I met its primary endpoint, showing a significant reduction in the rate of asthma exacerbations in people with higher levels of serum periostin or blood eosinophils, both biomarkers of airway inflammation. In addition, this study demonstrated a significant improvement in lung function as measured by forced expiratory volume in one second (FEV1). The observed effect in the primary and secondary endpoints, however, was less than seen in the lebrikizumab phase II trials.

In contrast, the exacerbation reduction results observed in LAVOLTA II did not meet statistical significance. No new safety signals were observed in either study.3,4

“We were hopeful these identical studies would confirm the phase II results because there is still a significant unmet need for people with severe asthma,” said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development at Roche. “These data require further interpretation and analyses are ongoing to better understand the results and determine next steps.”

Results from the studies will be submitted for presentation at forthcoming medical meetings.
About LAVOLTA

LAVOLTA I and II are two identical, randomised, multicentre, placebo-controlled phase III studies designed to evaluate the efficacy and safety of lebrikizumab in people with severe asthma that is uncontrolled despite standard-of-care treatment with an inhaled corticosteroid and a second controller medication. The studies together included more than 2,100 people across 28 countries.

The primary endpoint of both studies was the rate of asthma exacerbations over 52 weeks. The evaluation of the primary and secondary endpoints was based on a subgroup of people with higher levels of serum periostin or blood eosinophils.

About asthma

Asthma is a chronic disease of the lungs involving inflammation and narrowing of the airways. Chronic lung inflammation is associated with airway hyper-responsiveness – an exaggerated constrictive reaction in the airways of the lungs to a variety of factors including inhaled allergens and cold air – and recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night or in the early morning. Asthma is associated with variable airflow obstruction within the lung that is often reversible either spontaneously or with treatment.

The global prevalence of asthma is expected to reach 400 million by 2025, and a quarter of a million people worldwide are estimated to die every year from the disease. If uncontrolled, asthma places substantial limitations on daily life and is sometimes fatal. Current treatments may include daily use of an inhaled or oral corticosteroid and other controller medication such as long-acting bronchodilators.

About lebrikizumab

Lebrikizumab is a novel, humanised monoclonal antibody designed to specifically block the action of interleukin-13 (IL-13), a cytokine that is a key contributor to airway inflammation and asthma disease processes in some people. Clinical studies in asthma, chronic obstructive pulmonary disease (COPD), atopic dermatitis (AD) and idiopathic pulmonary fibrosis (IPF) are ongoing.

About eosinophils

Eosinophils are inflammatory cells that can be present in increased numbers in the airways and blood of people with asthma (eosinophilia). Airway eosinophilia has been associated with key features of asthma. IL-13 plays
an important role in attracting eosinophils from the blood to the airway, hence contributing to airway eosinophilia.\(^8,9\)

**About periostin**

Periostin is a protein that has been identified as a key biomarker of inflammation in certain types of asthma. Its presence can be measured with a blood test. In people with asthma who have high levels of serum periostin, IL-13 appears to be a major contributor to their airway inflammation. An elevated serum periostin level has also been shown to be a predictor of airway eosinophilia, a prominent feature of asthma.\(^9\)

**About Roche in respiratory diseases**

Roche is committed to transforming care for patients with severe respiratory diseases. The Roche Group’s 25 years of respiratory experience includes medicines such as Xolair® (omalizumab) in severe asthma marketed by Genentech in the US, Pulmozyme® (dornase alfa) for cystic fibrosis, and Esbriet® (pirfenidone) for idiopathic pulmonary fibrosis. Roche also markets Tarceva® (erlotinib), Avastin® (bevacizumab) and Alecensa® (alectinib) for the treatment of specific types of lung cancer. The lebrikizumab development programme reflects Roche’s personalised healthcare approach, which includes the use of periostin and eosinophils as biomarkers to identify those patients who are more likely to have more severe disease and may better respond to treatment with lebrikizumab.

**About Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives.

Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials
and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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References