New Roche Esbriet data show clinical benefits of continued and long-term treatment in patients with idiopathic pulmonary fibrosis (IPF)

- A pooled analysis from three phase III studies - ASCEND and CAPACITY I and II - show a 38% reduction in risk of death after up to two years on Esbriet treatment
- These data are the first long-term results to show continued reduction in risk of death for IPF patients
- Additionally, an ad-hoc analysis of the pooled ASCEND and CAPACITY I and II studies show clinical benefits of continued Esbriet treatment after hospitalisation

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new clinical data and abstracts on Esbriet® (pirfenidone) in the treatment of idiopathic pulmonary fibrosis (IPF) are being presented at the European Respiratory Society (ERS) congress in Amsterdam. A pooled analysis from the ASCEND and CAPACITY phase III studies showed a 38% reduction in risk of death (p=0.0515) in IPF patients who stayed on Esbriet treatment up to two years (120 weeks) compared with placebo.

“These new data demonstrate Esbriet’s ability to reduce the risk of death for patients with this severe, progressive lung disease,” said Sandra Horning, M.D., Roche’s Chief Medical Officer and Head of Global Product Development. “As the first long-term mortality data in IPF patients treated with Esbriet, these results provide valuable information to help physicians and patients make decisions about their treatment.”

Previously reported data at one year showed the risk of mortality was reduced by 48% after treatment with Esbriet, a statistically significant result. The new data at 120 weeks show a strong trend in a reduced risk of death with long-term Esbriet treatment in IPF.

Also presented at the ERS, an ad-hoc analysis of the pooled ASCEND and CAPACITY data showed patients who are hospitalised within the first six months of treatment saw their risk of disease progression (≥10% decline in lung function) or death reduced by more than two-thirds (relative difference = 72.2%) at one year
by remaining on Esbriet treatment, compared with placebo. These clinical results show the benefits of continuing treatment. It is one of the first analyses on this topic and is of particular value for physicians and patients, as there is currently limited information to inform clinical decisions.

“These additional data show that continuing treatment with Esbriet after early hospitalisation may help slow disease progression,” said Horning.

Both analyses reinforced the well-established safety profile of Esbriet and were consistent with previous trial results. For more than four years, Esbriet has been available to physicians and IPF patients in Europe and was approved last year in the United States. More than 20,000 IPF patients worldwide have been treated with Esbriet for the equivalent of a year.

About IPF
IPF is a fatal disease caused by irreversible, progressive scarring (fibrosis) of the lungs, which makes breathing difficult and prevents the heart, muscles and vital organs from receiving enough oxygen to work properly. The disease can advance quickly or slowly, but eventually the lungs will harden and stop working altogether. IPF’s rapid decline is worse than that of most cancers; in a recent study, only patients with lung and pancreatic cancer were shown to have a worse survival.

Approximately 100,000 people in the United States and 110,000 people in Europe have IPF. The cause is unknown, and there is no cure. A limited number of patients with IPF undergo lung transplantation. IPF inevitably causes shortness of breath and destruction of healthy lung tissue. Half of IPF patients fail to survive just three years following diagnosis, and the five-year survival rate is approximately 20-40%. IPF typically occurs in people over the age of 45, and tends to affect slightly more men than women.

About Esbriet
Esbriet is an oral medicine approved for the treatment of IPF and is available in more than 38 countries worldwide. The mechanism of action of Esbriet is not fully understood, although it is believed to interfere with the production of transforming growth factor (TGF)-beta, a small protein in the body involved in how cells grow and produce scars (fibrosis), and tumour necrosis factor (TNF)-alpha, a small protein that is involved in inflammation. Esbriet has Orphan Drug designation and was approved for use in Europe in 2011 in adults with mild-to-moderate IPF and in the US in patients with IPF in October 2014.
Esbriet was approved for the treatment of IPF on the basis of the largest clinical trial programme in IPF to date, including three phase III trials (ASCEND and CAPACITY I and II) with a total of 1,247 patients. In one clinical study, after one year of treatment, Esbriet slowed the loss of lung function by about half (48%) and more than doubled (2.3 times; 63 patients treated with Esbriet vs 27 patients on placebo) the number of people who did not lose any lung function. Esbriet has been shown to have a well-established safety profile.

Esbriet is recommended for conditional use in IPF patients in the ATS / ERS / JRS / ALAT treatment guidelines published in July 2015. Pirfenidone has been marketed as Pirespa since 2008 in Japan and since 2012 in South Korea by Shionogi & Co Ltd. Under different trade names, pirfenidone is also approved for the treatment of IPF in China, India, Argentina and Mexico. Roche acquired InterMune and its lead asset Esbriet in September 2014 and continues to expand access to Esbriet in more than 55 countries worldwide.

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. Lebrikizumab is in phase III clinical trials for severe uncontrolled asthma and targets IL-13. It reflects Roche’s personalised healthcare approach and includes periostin as a biomarker to identify those patients who are more likely to have a more severe disease and may better respond to treatment with lebrikizumab. Our leadership in bringing personalised healthcare to lung cancer patients includes Tarceva (erlotinib) as well as investigational medicines alectinib and atezolizumab. Avastin (bevacizumab) is also approved for use in lung cancer.

About Roche
Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-eight medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.
In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. 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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