Media Release

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FDA approves Esbriet® (pirfenidone) for the treatment of idiopathic pulmonary fibrosis (IPF) in the United States

- **Approximately 100,000 people in the United States have IPF, an irreversible and fatal lung disease**[1]
- **Esbriet® approved under FDA's breakthrough designation program**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved Esbriet® (pirfenidone) as a treatment for idiopathic pulmonary fibrosis (IPF) in the United States. IPF is a fatal disease caused by 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.[2]

"This is a historic day for the people and their families in the United States who live with this deadly, incurable disease," said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development. "With today's approval of Esbriet in the United States, people with IPF finally have an FDA-approved medicine that may slow the worsening of the disease."

The approval of Esbriet is based on data from a large, placebo-controlled Phase III study known as ASCEND and is supported by two other large Phase III trials known as CAPACITY 1 and 2. In the ASCEND study, more patients who received Esbriet had a delay in the decline of lung function compared to those who received placebo as defined by the primary endpoint of percent change in Forced Vital Capacity (FVC), a measure of how well the lungs work based on the amount of air one can exhale with force after inhaling as deeply as possible.
The most serious adverse events observed in people who received Esbriet compared to those who received placebo were: elevations in liver enzymes found in the blood (a sign of liver damage; 3.7 percent vs. 0.8 percent), sensitivity to light or rash (9.0 percent vs. 1.0 percent) and gastrointestinal (GI) side effects that

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caused 2.2 percent of patients to discontinue treatment compared to 1.0 percent of those who received placebo.

The approval of Esbriet in the United States would not have been possible without the 12 years of effort by InterMune, a Brisbane, California-based biotechnology company that dedicated itself to developing medicines for IPF and other serious diseases related to fibrosis. On September 29, 2014, Roche announced that they completed the acquisition of InterMune after a definitive merger agreement on August 24, 2014.

“Until today, the 100,000 people with IPF living in the United States did not have an FDA-approved treatment,” said Jonathan Leff, M.D., Executive Vice President of Research and Development at InterMune. “Today's approval would not have been possible without the courage of patients, their families and the medical community that participated in the clinical studies of Esbriet.”

About IPF

Approximately 100,000 people in the United States and 80,000 to 110,000 in Europe have IPF, an irreversible and ultimately fatal disease characterized by progressive loss of the ability of the lungs to absorb oxygen due to scarring.[1,2] The cause is unknown and there is no cure. IPF inevitably causes shortness of breath and destruction of healthy lung tissue, although some people may experience periods of stability with the disease.[2-5] The median survival time from diagnosis is two to five years, and the five-year survival rate is approximately 20 to 40 percent.[2,6] IPF typically occurs in people over the age of 45, and tends to affect slightly more men than women.[1]

About Esbriet

Esbriet is an oral medicine for the treatment of idiopathic pulmonary fibrosis. The mechanism of action of Esbriet is not 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 Tumor Necrosis Factor (TNF)-alpha, a small protein that is involved in inflammation. Earlier this year, the FDA granted Esbriet Breakthrough Therapy Designation based on the positive data from the ASCEND clinical trial and the serious and life-threatening nature of IPF. It has also been granted Orphan Drug designation in the United States.

Esbriet was developed for use by InterMune in the United States, Europe and other countries. It was granted marketing authorization in the European Union (EU) in 2011 for the treatment of adults with mild to

moderate IPF in all 28 EU member countries, and has since been approved in Norway, Iceland and Canada.

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-four medicines developed by Roche are included in the World Health Organisation Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2013 the Roche Group employed over 85,000 people worldwide, invested 8.7 billion Swiss francs in R&D and posted sales of 46.8 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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