Investor Update

Basel, 27 June 2017

Fewer pills, more flexibility in dosing: Roche’s new Esbriet tablet formulation approved in Europe for mild to moderate idiopathic pulmonary fibrosis (IPF)

- New immediate-release tablet formulation of Esbriet offers a reduced pill burden for patients with idiopathic pulmonary fibrosis (IPF)
- People with IPF now have the option of taking one Esbriet tablet three times per day, instead of three capsules three times per day
- IPF is a rare, incurable lung disease. On average, patients live two to five years following an IPF diagnosis

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the European Commission (EC) has approved a new tablet formulation of Esbriet® (pirfenidone) for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF), a fatal condition that causes irreversible, progressive scarring of the lungs.

Esbriet has been shown to slow the progression of IPF, and the new tablet formulation, available as an 801 mg or 267 mg tablet, is designed to provide additional treatment options for people living with the disease.

The new 801 mg tablet can reduce the pill burden; patients can take one tablet three times per day instead of three capsules three times per day. The film-coated 267 mg tablet that has been introduced is smaller than the 267 mg capsule and might be easier to swallow. At equal doses, the new tablet formulation is bioequivalent to the currently available capsule version of Esbriet.

“We are pleased to launch this important new formulation for people living with IPF, as part of our mission to improve the lives of patients with this devastating disease,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We are committed to helping people living with IPF, and being able to provide a tablet formulation of Esbriet gives patients more options for the management of their condition.”
IPF is a devastating and poorly understood condition that requires treatment as early as possible to help people with the disease maintain independence and live longer, better lives.\(^6\) Data have shown that treatment with Esbriet significantly reduced the risk of death at 52 weeks by 48% in people with IPF compared with placebo (\(p=0.01\)).\(^7\) At Week 52, a decline from Baseline in percent predicted FVC of \(\geq10\%\) or death was seen in 17% of patients receiving Esbriet compared to 32% receiving placebo.\(^8\) Furthermore, Esbriet significantly reduced the decline in 6-minute-walk test distance, a measure of functional disease status, by 44.2% compared to placebo.\(^7\)

The new Esbriet tablet formulation is already approved by the United Stated (US) Food and Drug Administration (FDA) and available in the US. Following this EC approval, Roche expects to begin launching the tablet formulation in a number of European markets throughout 2017.

**About idiopathic pulmonary fibrosis**

Idiopathic pulmonary fibrosis (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.\(^2,9\) The disease can advance quickly or slowly, but eventually the lungs will harden and stop working altogether.\(^2\) People with IPF experience a more rapid decline than most cancer patients; in a recent study, only people with lung and pancreatic cancer were shown to have worse survival.\(^10\)

Approximately 100,000 people in the United States\(^11\) and 110,000 people in Europe have IPF.\(^12\) The cause is unknown, and there is no cure. A limited number of people with IPF undergo lung transplantation. IPF inevitably causes shortness of breath and destruction of healthy lung tissue. Half of IPF people fail to survive just three years following diagnosis, and the five-year survival rate is approximately 20-30\%.\(^13\) IPF typically occurs in people over the age of 45, and tends to affect more men than women.\(^14,15\)

**About Esbriet**

Esbriet is an oral medicine approved for the treatment of IPF and is available in more than 40 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\(^{16}\) and in the US in people with IPF in October 2014.\(^{17}\) In early 2017, the US Food and Drug Administration (FDA) approved the Esbriet 801 mg and 267 mg tablets as new options for administering the medicine for the treatment of IPF. The new 801 mg tablets, which are now available in the US, offer people with IPF a maintenance option for taking Esbriet with fewer pills per day.

Esbriet is approved in Europe for the treatment of IPF on the basis of four Phase 3, multicentre, randomised, double-blind, placebo-controlled studies in patients with IPF. Three of the Phase 3 studies (ASCEND and CAPACITY 004 and 006) were multinational, and one (SP3) was conducted in Japan. Esbriet has a well-established safety profile, the most common adverse events being related to the gastrointestinal tract (nausea, diarrhoea, dyspepsia), skin (rash and photosensitivity reaction), as well as fatigue and anorexia.

Esbriet is conditionally recommended for use in people with IPF in the ATS / ERS / JRS / ALAT treatment guidelines published in July 2015.\(^{18}\) 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 countries worldwide.

**About Roche in Respiratory Diseases**

Roche is committed to transforming care for people with severe respiratory diseases. The Roche Group’s nearly 30 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 medicines Alecensa® (alectinib), Avastin® (bevacizumab), Tarceva® (erlotinib) and Tecentriq® (atezolizumab) are approved for the treatment of specific types of lung cancer.
About Roche

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

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. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty 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 eight years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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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Roche Investor Relations

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraebere@roche.com

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Tamer Farhan
Phone: +41 61 68-82552
e-mail: tamer.farhan@roche.com
Dr. Birgit Masjost  
Phone: +41 61 68-84814  
e-mail: birgit.masjost@roche.com

Dr. Susann Weissmüller  
Phone: +41 61-68-75619  
e-mail: susann.weissmueller@roche.com

Investor Relations North America  
Neera Dahiya Ravindran, MD  
Phone: +1 650 491 5281  
e-mail: ravindran.neera@gene.com

Loren Kalm  
Phone: +1 650 225 3217  
e-mail: kalm.loren@gene.com
References


5. Roche data on file


