

Basel, 10 April 2017

## **Phase III study shows Roche's Alecensa was superior to crizotinib in a specific type of lung cancer**

- **Second Phase III head-to-head study that showed that Alecensa helped people with advanced ALK-positive non-small cell lung cancer (NSCLC)**
- **Results showed that people treated with Alecensa lived significantly longer without their disease progressing compared to crizotinib when given as initial (first-line) treatment**
- **Data will be submitted to global health authorities and presented at an upcoming medical meeting**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the global, randomised phase III ALEX study met its primary endpoint and showed that Alecensa® (alectinib) as an initial (first-line) treatment significantly reduced the risk of disease worsening or death (progression-free survival, PFS) compared to crizotinib in people with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC). This is the second phase III trial to show that Alecensa was superior as an initial treatment compared to crizotinib in this type of lung cancer. The safety profile of Alecensa was consistent with that observed in previous studies, with no new or unexpected adverse events.

“Our goal is to transform the standard of care and we are excited to share these results with the lung cancer community”, said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. “As part of its Breakthrough Therapy Designation, we hope to bring Alecensa as an initial treatment for people with ALK-positive NSCLC as soon as possible and will discuss these data with global health authorities.”

Full data from the ALEX study will be presented at an upcoming medical meeting and submitted to global health authorities, including the United States Food and Drug Administration (FDA), which in September 2016 granted Alecensa Breakthrough Therapy Designation (BTD) for the treatment of people with advanced ALK-positive NSCLC who have not received prior treatment with an ALK inhibitor.

Alecensa is approved as a monotherapy (alone) for people with ALK-positive NSCLC who have progressed or are intolerant to crizotinib in Europe, the U.S. and nine other countries globally. Alecensa is also approved in Japan for people whose tumours were advanced, recurrent or could not be removed completely through surgery (unresectable). In the US, Alecensa was granted accelerated approval by the FDA in December 2015 for the treatment of people with ALK-positive NSCLC who have progressed on or are intolerant to crizotinib. The ALEX study is part of the company's commitment to convert the current accelerated approval of Alecensa in people with ALK-positive, metastatic NSCLC who have progressed on or are intolerant to crizotinib to a full approval as an initial treatment.

In the European Union, Alecensa was granted conditional marketing authorisation in February 2017 for the monotherapy treatment of people with ALK-positive NSCLC previously treated with crizotinib.<sup>2</sup> The ALEX study is also acts as the post-authorisation safety study to meet the specific obligation study to convert the conditional approval into a full approval in the EU for people with ALK-positive, advanced NSCLC previously treated with crizotinib.

Approximately 75,000 people globally are diagnosed with ALK-positive NSCLC every year. It is a distinct form of lung cancer commonly diagnosed in younger people (median age 52).<sup>1</sup> Approximately 54% of cases are found in women.<sup>2</sup> ALK-positive NSCLC is also generally found in those with a light or non-smoking history.<sup>3</sup>

#### **About the ALEX study<sup>4</sup>**

ALEX (NCT02075840) is a randomised, multicentre, open-label phase III study evaluating the efficacy and safety of Alecensa versus crizotinib in treatment-naïve people with ALK-positive NSCLC whose tumours were characterised as ALK-positive by the VENTANA ALK (D5F3) CDx Assay, a companion immunohistochemistry (IHC) test developed by Roche Tissue Diagnostics. People were randomised (1:1) to receive either Alecensa or crizotinib. The primary endpoint of the ALEX study is progression-free survival (PFS) as assessed by the investigator and secondary endpoints include: Independent Review Committee (IRC)-assessed PFS, time to Central Nervous System (CNS) progression, objective response rate (ORR; as defined by RECIST criteria), duration of response, overall survival, health-related quality of life (HRQoL) and safety. The multicentre study was conducted in 303 people across 161 sites in 31 countries.

### **About Alecensa**

Alecensa (RG7853/AF-802/RO5424802/CH5424802) is an oral medicine created at Chugai Research Laboratories and is being developed for people with NSCLC whose tumours are identified as ALK-positive. ALK-positive NSCLC is often found in younger people who have a light or non-smoking history.<sup>3</sup> It is almost always found in people with a specific type of NSCLC called adenocarcinoma.<sup>3</sup> Alecensa is currently approved in the United States, Europe, Kuwait, Israel, Hong Kong, Canada, South Korea, Switzerland, India, Australia and Taiwan for the treatment of advanced (metastatic) ALK-positive NSCLC whose disease has worsened after, or who could not tolerate treatment with, crizotinib and in Japan for ALK-positive NSCLC people.

The global phase III ALEX study of Alecensa includes a companion test developed by Roche Diagnostics. Alecensa is marketed in Japan by Chugai Pharmaceutical, a member of the Roche Group.

### **About Roche in lung cancer**

Lung cancer is a major area of focus and investment for Roche, and we are committed to developing new approaches, medicines and tests that can help people with this deadly disease. Our goal is to provide an effective treatment option for every person diagnosed with lung cancer. We currently have four approved medicines to treat certain kinds of lung cancer and more than ten medicines being developed to target the most common genetic drivers of lung cancer or to boost the immune system to combat the disease.

### **About Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve patient'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. 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 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](http://www.roche.com).

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### **Additional information**

- Roche in Oncology: [www.roche.com/media/media\\_backgrounder/media\\_oncology.htm](http://www.roche.com/media/media_backgrounder/media_oncology.htm)

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### **References**

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<sup>1</sup> Shaw A, et al. Clinical features and outcome of patients with Non-Small-Cell Lung Cancer who harbor EML4-ALK. *J Clin Oncol.* 2009; 27(26): 4247-4253.

<sup>2</sup> Takeuchi K, et al. Prospective and clinical validation of ALK immunohistochemistry: results from the phase I/II study of alectinib for ALK-positive lung cancer (AF-001JP study). *Ann Onc.* 2016;27:185-192.

<sup>3</sup> Gridelli C, et al. ALK inhibitors in the treatment of advanced NSCLC. *Cancer Treatment Reviews.* 2014;40:300-306.

<sup>4</sup> ClinicalTrials.gov. [Internet; cited 2017 Mar 29]. Available from: <https://clinicaltrials.gov/ct2/show/NCT02075840>.