

Basel, 1 September 2016

## **Phase III study showed Roche's cancer immunotherapy TECENTRIQ (atezolizumab) helped people with a specific type of lung cancer live significantly longer compared to chemotherapy**

- **TECENTRIQ showed significant improvement in overall survival for people regardless of their PD-L1 status**
- **Data will be discussed with global health authorities, including the U.S. Food and Drug Administration (FDA)**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced positive results for TECENTRIQ® from the Phase III study, OAK. The study met its co-primary endpoints and showed a statistically significant and clinically meaningful improvement in overall survival (OS) compared with docetaxel chemotherapy in people with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease progressed on or after treatment with platinum-based chemotherapy. Adverse events were consistent with what has been previously observed for TECENTRIQ. Roche looks forward to presenting full results at an upcoming medical meeting in 2016.

“These results add to the growing body of evidence that supports the role of TECENTRIQ as a potential new treatment for specific types of advanced NSCLC,” said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. “This is very encouraging news for people living with this disease because lung cancer is the leading cause of cancer deaths around the world. We hope to bring this treatment option to patients as soon as possible.”

The FDA granted Breakthrough Therapy Designation (BTD) for TECENTRIQ for the treatment of people with PD-L1 (programmed death-ligand 1) positive non-small cell lung cancer (NSCLC) whose disease has progressed during or after platinum-based chemotherapy (and appropriate targeted therapy for those with an EGFR mutation-positive or ALK-positive tumour). Roche's Biologics Licence Application (BLA) for NSCLC was granted Priority Review with an action date of 19 October 2016.

Roche has eight Phase III lung studies underway evaluating TECENTRIQ alone or in combination with other treatments in patients with early and advanced stages of lung cancer.

### **About the OAK study**

OAK is a Phase III, global multicentre open-label randomised controlled study, evaluating the efficacy and safety of TECENTRIQ compared with docetaxel in patients with locally advanced or metastatic NSCLC whose disease progressed on or after treatment with platinum-containing chemotherapy.

- The study's co-primary endpoints were overall survival in:
  - All people randomised to treatment in the study (intention-to-treat or ITT population);
  - PD-L1 selected subgroup of people
- PD-L1 expression was assessed on both tumour cells (TC) and tumour-infiltrating cells (IC) with an investigational immunohistochemistry (IHC) test based on the SP142 antibody being developed by Roche Tissue Diagnostics, and was defined as people whose tumours were determined to express PD-L1 with an IHC score of TC1/2/3 or IC1/2/3.
- Secondary endpoints included objective response rate (ORR), progression-free survival (PFS), and duration of response (DOR).

A total of 1225 patients were enrolled and randomised 1:1 to receive either docetaxel (75 mg/m<sup>2</sup> intravenous infusion) or TECENTRIQ (1200 mg intravenous infusion) every three weeks. Treatment on TECENTRIQ continued as long as patients experienced clinical benefit as assessed by the investigator or until unacceptable toxicity. The primary efficacy analysis was based on the first 850 randomised patients, and the secondary efficacy analysis will include all 1,225 randomised patients.

### **About non-small cell lung cancer**

Lung cancer is the leading cause of cancer death globally. Each year 1.59 million people die as a result of the disease; this translates into more than 4,350 deaths worldwide every day. Lung cancer can be broadly divided into two major types: NSCLC and small cell lung cancer. NSCLC is the most prevalent type, accounting for around 85% of all cases.

### **About TECENTRIQ (atezolizumab)**

TECENTRIQ is a monoclonal antibody designed to target and bind to a protein called PD-L1 (programmed death ligand-1), which is expressed on tumour cells and tumour-infiltrating immune cells. PD-L1 interacts with PD-1 and B7.1, both found on the surface of T cells, causing inhibition of T cells. By blocking this interaction, TECENTRIQ may enable the activation of T cells, restoring their ability to effectively detect and

attack tumour cells.

TECENTRIQ is the first and only anti-PD-L1 cancer immunotherapy approved by the FDA, and is indicated for the treatment of people with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-based chemotherapy, or whose disease has worsened within 12 months of receiving platinum-based chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant). This indication for TECENTRIQ is approved under accelerated approval based on tumour response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

#### **About Roche in cancer immunotherapy**

For more than 50 years, Roche has been developing medicines with the goal to redefine treatment in oncology. Today, we're investing more than ever in our effort to bring innovative treatment options that help a person's own immune system fight cancer.

#### **About personalised cancer immunotherapy (PCI)**

The aim of personalised cancer immunotherapy (PCI) is to provide patients and physicians with treatment options tailored to the specific immune biology associated with a person's individual tumour. The purpose is to inform treatment strategies which provide the greatest number of people with a chance for transformative benefit. In the case of TECENTRIQ, the goal of PD-L1 as a biomarker is to explore PD-L1 expression on tumour cells and tumour infiltrating immune cells and how that correlates with clinical benefit either as a monotherapy or in combination, and across a broad range of tumour types. The Roche PCI research and development programme comprises more than 20 investigational candidates, ten of which are in clinical trials.

PCI is an essential component of how Roche delivers on the broader commitment to personalised healthcare.

To learn more about the Roche approach to cancer immunotherapy please follow this link:

[http://www.roche.com/research\\_and\\_development/what\\_we\\_are\\_working\\_on/oncology/cancer-immunotherapy.htm](http://www.roche.com/research_and_development/what_we_are_working_on/oncology/cancer-immunotherapy.htm)

#### **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](http://www.roche.com).

All trademarks used or mentioned in this release are protected by law.

### **Roche Group Media Relations**

Phone: +41 -61 688 8888 / e-mail: [roche.mediarelations@roche.com](mailto:roche.mediarelations@roche.com)

- Nicolas Dunant (Head)
- Catherine Dürr
- Ulrike Engels-Lange
- Anja von Treskow