

Basel, 10 May 2017

## **Roche provides update on phase III study of TECENTRIQ® (atezolizumab) in people with previously treated advanced bladder cancer**

- **IMvigor211 study did not meet its primary endpoint of overall survival (OS) compared to chemotherapy**
- **The safety profile was consistent with what has been previously observed for TECENTRIQ**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMvigor211 study that evaluated TECENTRIQ (atezolizumab) in people with locally advanced or metastatic urothelial cancer (mUC) whose disease progressed during or after treatment with a platinum-based chemotherapy (previously treated) did not meet its primary endpoint of overall survival (OS) compared to chemotherapy. The safety profile observed in IMvigor211 was consistent with what has been previously observed for TECENTRIQ.

“While these results are not what we had expected, we believe that TECENTRIQ will continue to play an important role in the treatment of people with advanced bladder cancer,” said Sandra Horning, M.D., chief medical officer and Head of Global Product Development. “We are committed to helping people with advanced bladder cancer and will discuss these data with health authorities.”

The results observed in people treated with TECENTRIQ in IMvigor211 were generally consistent with those observed in a similar group of people in the Phase II IMvigor210 study. The IMvigor211 data will be further examined in an effort to better understand these results, including the initial observation that the chemotherapy arm results were better than study design assumptions. Full data from IMvigor211 will be presented later this year.

TECENTRIQ was granted accelerated approval by the U.S. Food and Drug Administration (FDA) based on tumour response rate and duration of response in IMvigor210 for the treatment of people with locally advanced or 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). IMvigor211 was a randomised pivotal study designed to support full approval globally and to serve as the confirmatory study to convert the accelerated approval to full approval in the US.

The FDA recently granted accelerated approval to TECENTRIQ as an initial treatment for people with locally advanced or mUC who are not eligible for cisplatin chemotherapy. A Phase III pivotal study, IMvigor130 is currently ongoing in this population.

Roche has an extensive clinical trial development programme for TECENTRIQ, with more than 30 trials ongoing, 17 of which are ongoing or planned Phase III studies across several kinds of lung, kidney, skin, breast, colorectal, prostate, ovarian, bladder, and blood cancers. This includes trials evaluating TECENTRIQ both alone and in combination with other medicines.

#### **About the IMvigor211 study**

IMvigor211 is the first randomised Phase III study of TECENTRIQ compared to chemotherapy in people with advanced bladder cancer who were previously treated with a platinum-based chemotherapy. The study evaluated the efficacy and safety of TECENTRIQ compared to chemotherapy (vinflunine, paclitaxel or docetaxel) administered every three weeks in 931 people with previously-treated mUC who progressed during or following a platinum-based regimen. Eligible patients had an Eastern Cooperative Oncology Group performance status of 0-1, an evaluable tumor sample for centralised PD-L1 testing and had received at least one prior therapeutic regimens for mUC or who had developed mUC within 12 months of receiving platinum-based chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant). The primary efficacy endpoint was OS and key secondary endpoints include objective response rate, progression-free survival, duration of response and safety.

The primary efficacy endpoint, overall survival, was to be tested in a successive fashion in study populations defined by PD-L1 expression. The first population tested was people with the highest levels of PD-L1 expression (IC2/3), followed by those with any level of PD-L1 expression (IC1/2/3), and followed by the overall study population (Intention-To-Treat; ITT). Statistical significance needed to be achieved in the IC2/3 population in order to evaluate the IC1/2/3 population for statistical significance, and similarly achieved in the IC1/2/3 population in order to evaluate the overall study population for statistical significance.

### **About the IMvigor210 study**

IMvigor 210 is an open-label, multicenter, two-cohort Phase II study that evaluated the safety and efficacy of TECENTRIQ in people with locally advanced or mUC, regardless of PD-L1 expression. People in a cohort of the study whose disease had progressed during or following previous treatment with a platinum-based chemotherapy regimen, or who had disease progression within 12 months of treatment with a platinum-based neoadjuvant or adjuvant chemotherapy regimen (n=310) received a 1200-mg intravenous dose of TECENTRIQ on day one of 21-day cycles until unacceptable toxicity or either radiographic or clinical progression. The primary endpoint of the study was objective response rate (ORR) as assessed by an independent review facility (IRF) using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Secondary endpoints included duration of response (DOR).

### **About metastatic urothelial carcinoma**

Metastatic urothelial cancer (mUC) is associated with a poor prognosis and limited treatment options. Until TECENTRIQ's approval in the US in May 2016 there had been no major advances for more than 30 years. UC is the ninth most common cancer worldwide, with 430,000 new cases diagnosed in 2012, and it results in approximately 145,000 deaths globally each year. Men are three times more likely to suffer from UC, compared with women, and the disease is three times more common in developed countries than in less developed countries.

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

TECENTRIQ is a monoclonal antibody designed to bind with a protein called PD-L1. TECENTRIQ is designed to bind to PD-L1 expressed on tumour cells and tumour-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptors. By inhibiting PD-L1, TECENTRIQ may enable the activation of T cells. TECENTRIQ may also affect normal cells.

### **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 that provide the greatest number of people with a chance for transformative benefit. PCI encompasses the search for reliable biomarkers 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. 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 for improving 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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