Basel, 20 November 2017

Phase III IMpower150 study showed Roche's TECENTRIQ (atezolizumab) and Avastin (bevacizumab) plus chemotherapy significantly reduced the risk of disease worsening or death in the initial treatment of people with a type of advanced lung cancer

- **Data will be submitted to health authorities globally, including the US Food and Drug Administration (FDA) and European Medicines Agency (EMA)**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the Phase III IMpower150 study met its co-primary endpoint of progression-free survival (PFS) and demonstrated that the combination of TECENTRIQ® (atezolizumab) and Avastin® (bevacizumab) plus chemotherapy (paclitaxel and carboplatin) provided a statistically significant and clinically meaningful reduction in the risk of disease worsening or death (PFS) compared to Avastin plus chemotherapy in the first-line treatment of people with advanced non-squamous non-small cell lung cancer (NSCLC). Initial observations for the co-primary endpoint of overall survival (OS) are encouraging. These data are not fully mature and the next OS analysis is expected in the first half of 2018. Safety for the TECENTRIQ and Avastin plus chemotherapy combination appeared consistent with the known safety profile of the individual medicines, and no new safety signals were identified with the combination.

These data will be presented at the European Society for Medical Oncology (ESMO) Immuno Oncology Congress in Geneva, Switzerland in December 2017.

"We are extremely encouraged by these results and will submit these data to health authorities globally with the goal of bringing a potential new standard of care for the initial treatment of lung cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "In addition to first-line NSCLC, we are testing the ability of TECENTRIQ and Avastin to enhance the potential of the immune system to combat a broad range of other cancers."

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About the IMpower150 study

IMpower150 is a multicentre, open-label, randomised, controlled Phase III study evaluating the efficacy and safety of TECENTRIQ in combination with chemotherapy (carboplatin and paclitaxel) with or without Avastin in people with stage IV non-squamous NSCLC who had not been treated with chemotherapy for their advanced disease. It enrolled 1,202 people of which those with ALK* and EGFR mutations were excluded from the primary ITT analysis. People were randomised (1:1:1) to receive:

- TECENTRIQ plus carboplatin and paclitaxel (Arm A), or
- TECENTRIQ and Avastin plus carboplatin and paclitaxel (Arm B), or
- Avastin plus carboplatin and paclitaxel (Arm C, control arm).

During the treatment-induction phase, people in Arm A received TECENTRIQ administered intravenously at 1200 mg in combination with intravenous infusion of carboplatin and paclitaxel on Day 1 of a 3-week treatment cycle for 4 or 6 cycles. Following the induction phase, people received maintenance treatment with TECENTRIQ (1200 mg every 3 weeks) until loss of clinical benefit or disease progression.

People in Arm B received induction treatment with TECENTRIQ (1200 mg) and Avastin administered intravenously at 15 mg/kg in combination with intravenous infusion of carboplatin and paclitaxel on Day 1 of a 3-week treatment cycle for 4 or 6 cycles. People then received maintenance treatment with the TECENTRIQ Avastin regimen until disease progression (Avastin) or loss of clinical benefit/disease progression (TECENTRIQ).

People in Arm C received induction treatment with Avastin administered intravenously at 15 mg/kg plus intravenous infusion of carboplatin and paclitaxel on Day 1 of a 3-week treatment cycle for 4 or 6 cycles. This was followed by maintenance treatment with Avastin alone until disease progression.

The co-primary endpoints were PFS, as determined by the investigator using Response Evaluation Criteria in Solid Tumours Version 1.1 (RECIST v1.1), and OS. This analysis of the IMpower150 PFS endpoint was only statistically powered to demonstrate a comparison between Arm B versus Arm C.

The primary analysis of the co-primary PFS endpoint in IMpower150 was assessed in two populations: all randomised people without an ALK or EGFR genetic mutation (intention-to-treat wild-type**) and in a subgroup of people who had a specific biomarker (T-effector "Teff" gene signature expression). IMpower150 met its PFS co-primary endpoint per study protocol for both populations assessed.

About NSCLC

Despite recent advances in the treatment of NSCLC, there is still a need for new treatment options. Lung cancer is the leading cause of cancer death globally.[1] Each year 1.59 million people die as a result of the disease; this translates into more than 4,350 deaths worldwide every day.[2] 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.[2]

About TECENTRIQ (atezolizumab)

TECENTRIQ is a monoclonal antibody designed to bind with a protein called 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 has the potential to be used as a foundational combination partner with cancer immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers.

Currently, Roche has eight Phase III lung cancer studies underway, evaluating TECENTRIQ alone or in combination with other medicines.

TECENTRIQ is already approved in the European Union, United States and more than 50 countries for people with previously treated metastatic NSCLC and for people with locally advanced or metastatic urothelial cancer (mUC) who are not eligible for cisplatin chemotherapy, or who have had disease progression during or following platinum-containing therapy.

About Avastin (bevacizumab)

Avastin is a biologic cancer treatment approved in combination with chemotherapy for the first-line treatment of advanced NSCLC and, to-date, has helped over 500,000 patients lead longer lives. Avastin is considered a standard of care for the first-line treatment of advanced NSCLC and has been proven to significantly extend overall survival (OS). Avastin is currently approved in combination with any platinum-based chemotherapy in Europe, and with paclitaxel/carboplatin in the US, in first-line non-squamous NSCLC, based on results of the pivotal Phase III E4599 study. Avastin was the first medicine to help people with previously untreated advanced, non-squamous NSCLC live longer (OS) than one year when added to chemotherapy.

About the TECENTRIQ (atezolizumab) and Avastin (bevacizumab) combination

There is a strong scientific rationale to support the use of TECENTRIQ plus Avastin in combination. The TECENTRIQ and Avastin regimen may enhance the potential of the immune system to combat a broad range of cancers, including first-line advanced NSCLC. Avastin, in addition to its established anti-angiogenic effects, may further enhance TECENTRIQ's ability to restore anti-cancer immunity, by inhibiting VEGF-related immunosuppression, promoting T-cell tumour infiltration and enabling priming and activation of T-cell responses against tumour antigens.

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.

By applying our seminal research in immune tumour profiling within the framework of the Roche-devised cancer immunity cycle, we are accelerating and expanding the transformative benefits with TECENTRIQ to a greater number of people living with cancer. Our cancer immunotherapy development programme takes a comprehensive approach in pursuing the goal of restoring cancer immunity to improve outcomes for patients.

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

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 nine 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.

*ALK: Anaplastic Lymphoma Kinase

**EGFR WT: Epidermal Growth Factor Receptor Wild-Type

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