Media Release

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Pivotal Phase II study showed Roche's investigational immunotherapy atezolizumab shrank tumours in people with a specific type of lung cancer

- **Roche will discuss results with the U.S. Food and Drug Administration (FDA) as part of atezolizumab's Breakthrough Therapy Designation in lung cancer**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that in the large pivotal Phase II study, BIRCH, the investigational cancer immunotherapy atezolizumab (MPDL3280A; anti-PDL1) met its primary endpoint and shrank tumours (objective response rate; ORR) in people with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease expressed PD-L1 (Programmed Death Ligand-1). The study showed the amount of PD-L1 expressed by a person's cancer correlated with their response to the medicine. Adverse events were consistent with what has been previously observed for atezolizumab.

"We are encouraged by the number of people who responded to atezolizumab and maintained their response during the study, which is particularly meaningful for people who had received several prior treatments," said Sandra Horning, M.D., Chief Medical Officer and head of Global Product Development. "We plan to present results at an upcoming medical meeting and will discuss these data as well as results from our other lung cancer studies with health authorities to bring this medicine to patients as quickly as possible."

Earlier this year, the FDA granted atezolizumab a Breakthrough Therapy Designation for the treatment of people whose NSCLC expresses PD-L1 and who progressed during or after standard treatments (e.g. platinum-based chemotherapy and appropriate targeted therapy for EGFR mutation-positive or ALK-positive disease). This designation is designed to expedite the development and review of medicines intended to treat serious diseases. Roche have seven Phase III studies evaluating atezolizumab alone or in combination with other medicines as a potential new treatment for people with early and advanced stages of lung cancer.

About the BIRCH Study

BIRCH is an open-label, multicentre, single-arm Phase II study that evaluated the safety and efficacy of atezolizumab in 667 people with locally advanced or metastatic NSCLC whose disease expressed PD-L1. PD-L1 expression was assessed on both tumour cells (TC) and tumour-infiltrating immune cells (IC) with an investigational immunohistochemistry test (IHC) being developed by Roche Diagnostics. Eligibility criteria

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included people whose tumours were determined to express PD-L1 with an IHC score of TC2/3 or IC2/3. People in the study received a 1200-milligram intravenous dose of atezolizumab every 3 weeks. The primary endpoint of the study was ORR. Secondary endpoints included duration of response (DoR), overall survival (OS), progression-free survival (PFS) and safety.

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, which means 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 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 three approved medicines to treat certain kinds of lung cancer and more than 10 medicines being developed to target the most common genetic drivers of lung cancer or to boost the immune system to combat the disease.

About atezolizumab

Atezolizumab (also known as MPDL3280A; anti-PDL1) is an investigational monoclonal antibody designed to interfere with a protein called PD-L1. Atezolizumab is designed to target PD-L1 expressed on tumour cells and tumour-infiltrating immune cells, preventing it from binding to PD-1 and B7.1 on the surface of T cells. By inhibiting PD-L1, atezolizumab may enable the activation of T cells.

All studies of atezolizumab include the evaluation of an investigational IHC test that uses the antibody SP142 to measure PD-L1 expression on both tumour cells and infiltrating immune cells. The goal of PD-L1 as a biomarker is to identify those people most likely to benefit when treated with atezolizumab alone, and to determine which people may benefit most from a combination of atezolizumab and another medicine. There are 11 ongoing or planned Phase III studies of atezolizumab across certain kinds of lung, kidney, breast and bladder cancer.

About Roche in personalised cancer immunotherapy

For more than 30 years, Roche has been developing medicines with the goal to redefine treatment in oncology. Today, we're investing more than ever to bring personalised cancer immunotherapy (PCI) to people with cancer. The goal of PCI is to provide each person with a treatment tailored to harness his or her

own immune system to fight cancer. Roche is studying more than 20 investigational medicines, seven of which are in clinical trials. In every study we are evaluating biomarkers to identify which people may be appropriate candidates for our medicines.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. 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 chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. 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 roche.com.

Additional information

Roche in Oncology: www.roche.com/media/media_backgrounder/media_oncology.htm

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