Media Release

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FDA grants priority review for Roche's cancer immunotherapy atezolizumab in specific type of lung cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's Biologics License Application (BLA) and granted Priority Review for atezolizumab (anti-PDL1; MPDL3280A) for the treatment of people with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease expresses the protein PD-L1 (programmed death ligand-1), as determined by an FDA-approved test, and who have progressed on or after platinum-containing chemotherapy.

"In a study of atezolizumab in people with previously treated advanced lung cancer, PD-L1 expression correlated with how well they responded to the medicine," said Sandra Horning, M.D., chief medical officer and head of Global Product Development. "The goal of PD-L1 as a biomarker is to identify people most likely to benefit from atezolizumab alone."

Atezolizumab was granted Breakthrough Therapy Designation by the FDA in February 2015 for the treatment of people whose NSCLC expresses PD-L1 and whose disease progressed during or after standard treatments (e.g., platinum-based chemotherapy and appropriate targeted therapy for EGFR mutation-positive or ALK-positive disease). Breakthrough Therapy Designation is designed to expedite the development and review of medicines intended to treat serious or life-threatening diseases and to help ensure that people have access to them through FDA approval as soon as possible. The BLA submission for atezolizumab is based on results from clinical trials including the Phase II BIRCH study, and the FDA will make a decision on approval by Oct. 19, 2016. A Premarket Application (PMA) is also under review by the FDA for a companion immunohistochemistry (IHC) test developed by Roche Tissue Diagnostics.

This is the second BLA acceptance and priority review for atezolizumab. On 15th March, Roche announced that the FDA had accepted the company's BLA and granted Priority Review for atezolizumab for the treatment of people with locally advanced or metastatic urothelial carcinoma (mUC) who had disease progression during

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or following platinum-based chemotherapy in the metastatic setting, or whose disease worsened within 12 months of receiving platinum-based chemotherapy before surgery (neoadjuvant) or after surgery (adjuvant). Atezolizumab is also being studied in a number of other cancers.

About the BIRCH study

BIRCH is an open-label, multicenter, 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 for both tumor cells and tumor-infiltrating immune cells with an investigational IHC test based on the SP142 antibody. People in the study received a 1200-mg intravenous dose of atezolizumab every three weeks. 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), overall survival, progression-free survival 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; 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 atezolizumab

Atezolizumab (also known as MPDL3280A; anti-PDL1) is an investigational monoclonal antibody designed to bind with a protein called programmed death ligand-1 (PD-L1). Atezolizumab is designed to directly bind to PD-L1 expressed on tumour cells and tumour-infiltrating immune cells, blocking its interactions with PD-1 and B7.1 receptors. By inhibiting PD-L1, atezolizumab may enable the activation of T cells. Atezolizumab may also affect normal cells.

About personalised cancer immunotherapy

The aim of personalised cancer immunotherapy (PCI) is to provide individual patients with treatment options that are tailored to their specific needs. Our PCI research and development programme comprises more than 20 investigational candidates, eight of which are in clinical trials. All studies include the prospective evaluation of biomarkers to determine which people may be appropriate candidates for our medicines. In the case of atezolizumab, PCI begins with the PD-L1 (programmed death ligand-1) IHC assay

based on the SP142 antibody developed by Roche Tissue Diagnostics. The goal of PD-L1 as a biomarker is to identify those people most likely to experience clinical benefit with atezolizumab as a single agent versus those who may benefit more from combination approaches; the purpose is to inform treatment strategies which will give the greatest number of patients a chance for transformative benefit.The ability to combine atezolizumab with multiple chemotherapies may provide new treatment options to people across a broad range of tumours regardless of their level of PD-L1 expression.

Personalised Cancer Immunotherapy is an essential component of how Roche deliver on the broader commitment to personalised healthcare. 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 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.

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