Media Release

Basel, 2 February 2015

U.S. FDA grants Breakthrough Therapy Designation for Roche's investigational cancer immunotherapy MPDL3280A (anti-PDL1) in non-small cell lung cancer

Second FDA Breakthrough Therapy Designation for MPDL3280A following bladder cancer in 2014

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received a second Breakthrough Therapy Designation from the United States Food and Drug Administration (FDA) for its investigational cancer immunotherapy MPDL3280A (anti-PDL1). The designation was granted for the treatment of people with PD-L1-positive (Programmed Death-Ligand 1) 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).

"Lung cancer is the leading cause of cancer death globally, and we are pleased the FDA has granted breakthrough designation for MPDL3280A in non-small cell lung cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We are committed to personalised healthcare, developing medicines like MPDL3280A with companion tests that may help us identify those who may be appropriate candidates for our medicines. "

This breakthrough therapy designation is based on early results of MPDL3280A in people whose NSCLC was characterised as PD-L1-positive by an investigational test being developed by Roche. All studies of MPDL3280A are prospectively evaluating PD-L1 expression. Some studies will evaluate the medicine regardless of a tumor's PD-L1 status; other studies are evaluating the medicine only in people whose tumors are characterized as PD-L1 positive.

Breakthrough Therapy Designation is designed to expedite the development and review of medicines intended to treat serious diseases and to help ensure patients have access to them through FDA approval as soon as possible. The FDA granted the first Breakthrough Therapy Designation for MPDL3280A in metastatic bladder cancer in 2014. Ongoing pivotal studies of MPDL3280A include lung and bladder cancer, and we plan to initiate Phase III studies in additional tumor types this year.

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About MPDL3280A (anti-PDL1)

MPDL3280A (also known as anti-PDL1 and RG7446) is an investigational monoclonal antibody designed to interfere with a protein called PD-L1. MPDL3280A 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, MPDL3280A may enable the activation of T cells, restoring their ability to effectively detect and attack tumour cells.

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, non-small cell lung cancer (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 Roche in 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 in our effort to bring innovative treatment options that help a person's own immune system fight cancer. Our personalised cancer immunotherapy research and development programme comprises more than 20 investigational candidates, seven of which are in clinical trials. All studies include the evaluation of biomarkers to determine 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-four 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: http://www.roche.com/research_and_development/what_we_are_working_on/oncology.htm

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