Basel, 3 March 2014

Roche provides update on phase III study of onartuzumab in people with specific type of lung cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that an independent data monitoring committee has recommended that the phase III METLung study be stopped due to a lack of clinically meaningful efficacy.

The study evaluated if onartuzumab (MetMab) in combination with Tarceva (erlotinib) helped patients with previously treated, advanced non-small cell lung cancer (NSCLC) whose tumours were identified as MET-positive live longer compared to Tarceva alone. Overall adverse event rates were generally similar between the two groups. Data will be submitted for presentation at a forthcoming medical meeting.

"These results are disappointing because new options are needed for patients with lung cancer, the most common and deadly cancer worldwide," said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development. "We remain committed to helping patients with lung cancer and are studying several investigational medicines in this disease."

Roche is evaluating the implications of the METLung study results across the ongoing onartuzumab clinical programme.

About the METLung Study (NCT01456325)

- METLung is a Phase III, randomised, double-blind study evaluating the efficacy and safety profile of onartuzumab in combination with Tarceva in patients with previously treated (second- or third-line) advanced NSCLC identified to be MET-positive. The METLung study included a companion diagnostic immunohistochemistry (IHC) test that was co-developed with Ventana Medical Systems, Inc., a member of the Roche Group.
- Four hundred and ninety-nine patients were randomized to receive 150 mg of Tarceva taken daily plus either:
• Intravenous 15 mg/kg of onartuzumab every three weeks
• Intravenous placebo every three weeks
• The primary endpoint is overall survival. Secondary endpoints include progression-free survival, objective response rate and safety profile.
• The results announced today are from a pre-specified interim analysis.

About Lung Cancer
According to the World Health Organization, it is estimated that nearly 1.6 million people worldwide died of lung cancer in 2012; NSCLC accounts for 85 percent of all lung cancers.

About the MET Pathway
MET is a protein found on the surface of cells and acts as a receptor that binds to another protein called Hepatocyte Growth Factor (HGF), also known as "Scatter Factor". When HGF binds to MET, it causes MET proteins to form pairs (dimerise), which triggers a signalling cascade that tells cells to grow, divide, and spread to other parts of the body. Activation of the MET pathway has been proposed as a mechanism of tumour growth and spread (metastasis).

About Onartuzumab
Onartuzumab, an investigational monovalent (one-armed) monoclonal antibody designed to specifically target the MET receptor, is being studied in various cancers.

About Tarceva
Tarceva is a once-daily, oral non-chemotherapy treatment for the treatment of advanced or metastatic NSCLC. It has been shown to potently inhibit epidermal growth factor receptor (EGFR), a protein involved in the growth and development of cancers. Tarceva is a registered trademark of OSI Pharmaceuticals, LLC, a member of the Astellas global group of companies.

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 WHO Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

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