Roche to present important new data reflecting broad cancer pipeline at ASCO
First phase III data on obinutuzumab (GA101) in one of the most commonly diagnosed blood cancers
Early stage data on investigational anti-PD-L1 immunotherapy

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that important new data from clinical trials of several investigational and approved cancer medicines will be presented at the 49th Annual Meeting of the American Society of Clinical Oncology (ASCO), May 31 to June 4, 2013, in Chicago. At the meeting, Roche medicines will be highlighted in more than 275 abstracts, of which around one third were chosen for oral presentations. The collection of data at ASCO represents Roche’s breadth of research and includes:

- Next-generation biologics, such as glycoengineered antibodies and antibody-drug conjugates
- Immunotherapies designed to work with the body’s immune system
- Medicines designed to interfere with cancer cell growth and survival mechanisms
- Ongoing efforts to map the precise characteristics of tumour cells helping to determine which patients may respond to an experimental medicine

“We need treatments that attack cancer cells in a variety of ways to continue to make a difference to the lives of people facing this disease,” said Hal Barron M.D., chief medical officer and head, Global Product Development. “From harnessing a person’s immune system to delivering chemotherapy directly to a cancer cell, we believe the new data from our pipeline presented at ASCO have the potential to markedly change how cancer is treated.”

Full session details of the 2013 Annual Meeting can be found through the ASCO iPlanner:
Key Roche meeting highlights include:

**GA101: Unique investigational anti-CD20 antibody being tested in chronic lymphocytic leukemia (CLL)**

The phase III study CLL11, which is being conducted in close collaboration with the German CLL Study Group (GCLLSG), compared the combination of either GA101 or MabThera/Rituxan (rituximab) and standard chemotherapy (chlorambucil) to chlorambucil alone. The study included people with previously untreated chronic lymphocytic leukemia (CLL), the most common form of blood cancer, who were elderly and are often not able to tolerate existing standard options for CLL.

GA101 (RG7159, obinutuzumab) is the first investigational glycoengineered Type II anti-CD20 medicine, which means specific sugar molecules in GA101 were modified (using GlycoMAb technology) to change its interaction with the body’s immune cells with the goal of helping the immune system remove cancer cells from the body. In addition, as a type II anti-CD20 antibody, GA101 binds to CD20 with the aim of killing cancerous cells directly.

**Anti-PDL1: Immunotherapy**

Anti-PDL1 antibody MPDL3280A (RG7446): MPDL3280A is an investigational medicine designed to make cancer cells more vulnerable to the body’s own immune system by interfering with a protein called PD-L1. Several early stage studies on MPDL3280A in various cancer types will be presented, including data on potential biomarkers. These data will also be highlighted as part of ASCO’s official press program on May 15, 2013.

**ADCs: Antibody-drug conjugates**

Antibody-drug conjugates (ADCs): ADCs are designed to combine the specificity of antibodies with chemotherapy by seeking and attaching to certain types of cancer cells to deliver chemotherapy directly to them. The goal of ADCs is to reduce the effects of chemotherapy on healthy cells. Roche has nine ADCs in clinical trials. Early stage clinical data will be presented on investigational ADCs for lung, ovarian and prostate cancer; RG7599 (anti-NaPi2b), and RG7450 (anti-STEAP1) respectively.

**GDC-0199: Targeting cancer cell survival**

BCL-2 inhibitor GDC-0199 (RG7601, ABT-199): GDC-0199 is being studied in CLL and non-Hodgkin lymphoma (NHL), and is designed to work by interfering with the process by which some cancer cells survive, thereby promoting a natural death process known as apoptosis. Early data will be presented on GDC-0199 in CLL and non-Hodgkin lymphoma.
OncoGy pipeline with extensive biomarker and companion diagnostic program

The Roche oncology pipeline includes 40 investigational cancer medicines being studied in 600 clinical trials across a dozen types of cancer.

The combination of Roche pharmaceuticals and Roche diagnostics enables the company to research a broad spectrum of tumour biomarkers, each accompanied by a clinical diagnostic test. Every Roche oncology pipeline medicine includes a corresponding biomarker program that can help identify people who may be appropriate to receive a specific medicine. Currently, three out of four investigational medicines in the Roche oncology pipeline are being studied with a companion diagnostic test.

Avastin: Interfering with the tumour blood supply

Avastin (bevacizumab) is a medicine designed to specifically bind to the VEGF (vascular endothelial growth factor) protein. Avastin may block the tumour’s ability to communicate with nearby blood vessels and may prevent the tumour from connecting to the blood supply.

Results from more than 70 studies of Avastin are being presented at ASCO across several different cancers, including National Cancer Institute-sponsored phase III studies of cervical cancer and glioblastoma (GBM) and a Roche-sponsored phase III study in GBM. These studies are an example of Roche’s continued commitment to research on anti-angiogenesis across different tumour types.

List of studies referred to above:

GA101:
- Abstract #7004: Obinutuzumab (GA101) plus chlorambucil (Clb) or rituximab (R) plus Clb versus Clb alone in patients with chronic lymphocytic leukemia (CLL) and preexisting medical conditions (comorbidities): Final stage 1 results of the CLL11 (BO21004) phase III trial. Oral presentation, Tuesday, June 4, 9:15 – 9:30 AM CDT, in E354b

Anti-PDL1: Immunotherapy
- Abstract #3001: Biomarkers and associations with the clinical activity of PD-L1 blockade in a

- Abstract #3622: Clinical activity, safety and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic CRC, gastric cancer (GC), SCCHN or other tumours. Poster session, Sunday, June 2, 8:00 – 11:45 AM CDT in S Hall A2
- Abstract #8008: Clinical activity, safety and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). Oral presentation, Monday, June 3, 5:30 – 5:45 PM CDT in E Hall D2
- Abstract #9010: Clinical activity, safety and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with locally advanced or metastatic melanoma (mM). Symposium session, Sunday, June 2, 10:15 – 10:30 AM CDT in E Arie Crown Theater
- Abstract #4505: Clinical activity, safety and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with metastatic renal cell carcinoma (mRCC). Oral presentation, Saturday, June 1, 2:45 – 3:00 PM CDT in E Arie Crown Theater

ADCs:

- Abstract #5020: A phase I study of the safety and pharmacokinetics of DSTP3086S, an anti-STEAP1 antibody-drug conjugate (ADC), in patients (pts) with metastatic castration-resistant prostate cancer (CRPC). Poster session, Saturday, June 1, 8:00 AM – 12:00 PM CDT in E450a

Cell Communications / GDC-0199

- Abstract #7018: Updated results of a phase I first-in-human study of the BCL-2 inhibitor ABT-199 (GDC-0199) in patients with relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL). Poster session, Saturday, June 1, 8:00 AM – 12:00 PM CDT in S405

Avastin

Abstract #2005: Progression-free survival (PFS) and health-related quality of life (HRQoL) in AVAglio, a phase III study of bevacizumab (Bv), temozolomide (T) and radiotherapy (RT) in newly diagnosed glioblastoma (GBM) Oral presentation, Saturday, June 1, 4:30 – 4:45 PM CDT in E253

Abstract #2002: Tumor response based on adapted Macdonald criteria and assessment of pseudoprogression (PsPD) in the phase III AVAglio trial of bevacizumab (Bv) plus temozolomide (T) plus radiotherapy (RT) in newly diagnosed glioblastoma (GBM) Oral presentation, Saturday, June 1, 3:30 – 3:45 PM CDT in E253

Abstract #1: RTOG 0825: phase III double-blind placebo-controlled trial evaluating bevacizumab (Bev) in patients (Pts) with newly diagnosed glioblastoma (GBM) Plenary session, Sunday, June 2, 1:50 – 2:05 PM CDT in N Hall B1

The ADCs anti-NaPi2b and anti-STEAP1 are being developed utilizing Seattle Genetics’ ADC technology. GDC-0199 is being developed in collaboration with AbbVie.

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, infectious diseases, inflammation, metabolism 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 diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 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 www.roche.com.

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