Roche to present significant progress in advanced skin, lung and ovarian cancers at ASCO

- Progress in advanced skin and lung cancers through personalised healthcare
- New Phase III data for Avastin in ovarian cancer to be presented

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that data showing new personalised therapeutic approaches for people with skin and lung cancer, plus new data with Avastin (bevacizumab) in ovarian cancer, will be presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO).

At the meeting that is taking place June 3 to 7, 2011, in Chicago, Roche and Genentech’s investigational and approved cancer medicines will be featured in approximately 300 abstracts across more than 30 cancer types.

“Our goal is to develop cancer medicines that improve care in a way that is meaningful to patients and their doctors,” said Hal Barron M.D., Chief Medical Officer and head, Global Product Development. “Developing medicines that are tailored to a person’s specific cancer type is part of this strategy, and our data at ASCO will show that we are making substantial strides in the delivery of personalised healthcare.”

Key study results to be presented include:

- Vemurafenib (RG7204/PLX4032): Phase III data (BRIM3) in people with previously untreated metastatic melanoma with a mutated BRAF gene will be presented for the first time. Updated Phase II data (BRIM2) will also be presented.
- Tarceva (erlotinib): Important new data from EURTAC, the first Phase III study of Tarceva compared with chemotherapy in a Western population of people who had not previously been treated for a genetically distinct form of advanced lung cancer.
- MetMAb: Randomized Phase II data comparing MetMAb plus Tarceva to placebo plus Tarceva in people with advanced lung cancer with high or low levels of the Met receptor (Met diagnostic-positive or -negative).
- Avastin: Phase III data (OCEANS) in women with ovarian cancer that has progressed following initial treatment with platinum-based chemotherapy will be presented for the first time. New analyses from the
Phase III ICON7 study in women with newly diagnosed ovarian cancer and with poor prognosis will also be presented.

**New data on a personalised approach for people with a specific type of advanced skin cancer (metastatic melanoma)**

Data will be presented for the first time from the Phase III BRIM3 study of vemurafenib that met its co-primary endpoints showing a statistically significant improvement in survival and progression-free survival in people with previously untreated BRAF V600 mutation-positive metastatic melanoma. The safety profile was generally consistent with previous vemurafenib studies. Possible serious side effects of vemurafenib include liver problems, changes in heartbeat or very fast or abnormal heartbeats and allergic reactions.


A Phase II study, BRIM2, showed that vemurafenib shrunk tumours in more than half of people with previously treated BRAF V600 mutation-positive metastatic melanoma and that the safety profile was generally consistent with the Phase I study. Updated results from this study will be presented.

BRIM2: An open-label, multicenter Phase II study of RG7204 (PLX4032) in previously treated patients with BRAFV600E mutation-positive metastatic melanoma (Abstract #8509). Oral Presentation, Saturday 4 June, 16:00 - 16:15 CDT, Arie Crown Theater.

**Data on new approaches in advanced non-small cell lung cancer (NSCLC)**

EURTAC is the first Phase III study of Tarceva in a Western population with a genetically distinct form of advanced lung cancer. New data will be presented following an interim analysis that showed that people with EGFR activating mutation positive advanced NSCLC lived significantly longer without their disease getting worse when receiving Tarceva as initial therapy compared to platinum-based chemotherapy. A preliminary safety analysis showed the safety profile was consistent with previous studies of Tarceva.

EURTAC: Erlotinib vs. chemotherapy (CT) in advanced non-small-cell lung cancer (NSCLC) patients (p) with epidermal growth factor receptor (EGFR) activating mutations: Interim results of the European Tarceva vs. chemotherapy (EURTAC) Phase III randomized trial (Abstract #7503). Oral Presentation, Sunday 5 June, 09:30 - 09:45 CDT, Hall D1.
MetMAb is an investigational personalised medicine and a unique one-armed antibody that is designed to block the Met receptor, a switch that controls a key signalling pathway in lung cancer. Final efficacy results will be presented from a Phase II study (OAM4558g), including progression-free survival, overall survival and safety data. Details from this study will be provided in a press release on May 18 at 18:00 EDT (to be confirmed).

OAM4558g: Final efficacy results from OAM4558g, a randomized Phase II study evaluating MetMAb or placebo in combination with erlotinib in advanced NSCLC (Abstract #7505). Oral Presentation, Sunday 5 June, 10:00 - 10:15 CDT, Hall D1.

**New Phase III data on Avastin in advanced ovarian cancer**

Data will be presented from OCEANS, a Phase III study of Avastin in advanced ovarian cancer. OCEANS showed that women with platinum-sensitive ovarian cancer that had progressed following initial chemotherapy lived significantly longer without their disease getting worse when given Avastin in combination with chemotherapy (carboplatin and gemcitabine) followed by continued use of Avastin alone, compared to chemotherapy alone. No new safety findings were observed and adverse events were consistent with those seen in previous pivotal trials of Avastin.

OCEANS: A randomized, double-blinded, placebo-controlled, Phase III trial of chemotherapy with or without bevacizumab (BEV) in patients with platinum-sensitive recurrent epithelial ovarian (EOC), primary peritoneal (PPC), or fallopian tube cancer (FTC) (Abstract #LBA5007). ASCO press briefing, Saturday 4 June, 10:30 CDT, onsite press briefing room E271; Oral Presentation, Saturday 4 June, 16:15 - 16:30 CDT, room E354a.

Results of a new analysis from the ICON7 Phase III randomized trial of an Avastin-based regimen in women with newly diagnosed ovarian cancer will also be presented, including an interim analysis of overall survival and a subset analysis in women with poor prognosis.

ICON7: Result of interim analysis of overall survival in the GCIG ICON7 Phase III randomized trial of bevacizumab in women with newly diagnosed ovarian cancer (#LBA5006). ASCO press briefing, Saturday 4 June, 10:30 CDT, onsite press briefing room E271; Oral Presentation, Saturday 4 June, 16:00 - 16:15 CDT, room E354a.

Full session details for the 2011 Annual Meeting can be found through the ASCO ePlanner: [http://apps.asco.org/ePlanner/am2011.aspx](http://apps.asco.org/ePlanner/am2011.aspx)
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 EGFR, a protein involved in the growth and development of cancers. Tarceva is developed and commercialized by OSI in partnership with Genentech in the United States, Chugai in Japan and Roche in the rest of the world. Tarceva is a registered trademark of OSI Pharmaceuticals, LLC, a member of the Astellas global group of companies.

About EGFR in lung cancer
EGFR is a protein that extends across the cell membrane. The epidermal growth factor (EGF) binds to the part of the EGFR protein that sits on the outside of the cell. Binding leads to activation of the EGFR protein which triggers a complex signalling cascade inside the cell that leads to events including accelerated cell growth and division and development of metastases (tumour growth and spread to other parts of the body). Some NSCLC tumours have activating mutations in the EGFR gene, changing the structure of the EGFR proteins such that they have increased activity.

About Avastin: Over 5 Years of Transforming Cancer Care
With the initial approval in the USA for advanced colorectal cancer in 2004, Avastin became the first anti-angiogenic therapy made widely available for the treatment of patients with an advanced cancer. Today, Avastin is continuing to transform cancer care through its proven survival benefit (overall survival and/or progression free survival) across several types of cancer. Avastin is approved in the US and Europe for the treatment of advanced stages of colorectal cancer, breast cancer, non-small cell lung cancer and kidney cancer, and Avastin is also available in the US and over 31 other countries for the treatment of patients with glioblastoma (a type of brain cancer). Avastin is the only anti-angiogenic therapy available for the treatment of these numerous advanced cancer types, which collectively cause over 2.5 million deaths each year.

Avastin has made anti-angiogenic therapy a fundamental pillar of cancer treatment today – over a million patients have been treated with Avastin so far. A comprehensive clinical programme with more than 500 ongoing clinical trials is investigating the use of Avastin in over 50 tumor types (including colorectal, breast, non-small cell lung, brain, gastric, ovarian and others) and different settings (advanced or early stage disease).
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, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer 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 2010, Roche had over 80’000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

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