

Investor Update

Basel, 16 May 2012

Roche will report new data on important progress for people with advanced cancers at ASCO 2012

- First pivotal Phase III data on Roche's antibody-drug conjugate trastuzumab emtansine (T-DM1) in advanced HER2-positive metastatic breast cancer
- Phase III data on Avastin in advanced colorectal and ovarian cancers

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the company will present important new data from studies of several of its cancer medicines at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO), June 1 to 5, 2012, in Chicago. At the meeting, data on Roche's late-stage investigational and approved cancer medicines will be communicated in sessions that include 30 oral presentations.

"We have made significant progress for people with advanced cancers in the past year," said Hal Barron M.D., Chief Medical Officer and Head, Global Product Development. "At ASCO, we're pleased to present new data showing how we are moving forward in our goal of helping people who need new options in their fight against a number of advanced cancers, including data from EMILIA, our pivotal Phase III study on trastuzumab emtansine in HER2-positive metastatic breast cancer."

Key study results to be presented include:

- **Trastuzumab emtansine (T-DM1)**: Pivotal Phase III data (EMILIA) in people with HER2-positive metastatic breast cancer (mBC) who had previously received treatment with Herceptin and a taxane (chemotherapy) will be presented for the first time. These data will be submitted to global health authorities later this year. EMILIA will be presented in the plenary session at ASCO and will also be highlighted as part of ASCO's official press program.
- **Avastin (bevacizumab)**: Data will be presented from a Phase III study (ML18147) evaluating Avastin in combination with chemotherapy in people with metastatic colorectal cancer (mCRC) whose disease worsened following initial treatment with Avastin and a different chemotherapy. This study will be highlighted as part of ASCO's official press program.
- Data from AURELIA, the first Phase III study of Avastin plus chemotherapy in people with platinum-resistant recurrent ovarian cancer will be presented. This study will be highlighted as part of ASCO's official press program.
- **Zelboraf (vemurafenib)**: Updated overall survival results will be presented based on the most recent analysis from BRIM3, a phase III study in people with previously untreated BRAFV600E mutation-positive unresectable or metastatic melanoma.

First Phase III data on trastuzumab emtansine in advanced HER2-positive mBC

The introduction of Herceptin, the first targeted medicine for HER2-positive mBC, was a significant milestone for people with this aggressive breast cancer. However, additional effective medicines are still needed for this fatal disease. The Phase III **EMILIA** study evaluated trastuzumab emtansine in people with HER2-positive mBC who had previously received Herceptin and a taxane. As previously announced, the study showed that people who were treated with trastuzumab emtansine lived significantly longer without their disease getting worse (progression-free survival or PFS) compared to those who received lapatinib plus Xeloda (capecitabine). The safety profile of trastuzumab emtansine in the study was consistent with that seen in previous studies.

EMILIA: Primary results from EMILIA, a phase 3 study of trastuzumab emtansine (T-DM1) vs. capecitabine (X) and lapatinib (L) in HER2-positive locally advanced or metastatic breast cancer (MBC) previously treated with

trastuzumab (T) and a taxane. Abstract #LBA1. ASCO press briefing Saturday, June 2. Oral plenary presentation, Sunday, June 3, 1:45 – 2:00 PM CDT in N Hall B1.

Phase III data on Avastin in advanced colorectal and ovarian cancers

Data will be presented from the Phase III **ML18147** study. As previously announced, this study showed that people with mCRC who received Avastin plus standard chemotherapy as initial treatment (“first-line”) and then continued on Avastin with a different chemotherapy after their cancer worsened (“second-line”) lived significantly longer (overall survival or OS) than people who received chemotherapy only second-line. No new safety findings were observed and adverse events were consistent with those seen in previous trials of Avastin in mCRC.

ML18147: Bevacizumab (BEV) plus chemotherapy (CT) continued beyond first progression in patients with metastatic colorectal cancer (mCRC) previously treated with BEV + CT: Results of a randomized Phase III intergroup study. Abstract #CRA3503. ASCO press briefing Saturday, June 2. Oral presentation, Sunday, June 3, 10:45 AM – 11:00 AM CDT in E Hall D1.

Advanced ovarian cancer is an aggressive disease that unfortunately gets worse for many women even after initial treatment and, for some, the disease will become resistant to platinum-based chemotherapy. For these women there are only limited treatment options available. The **AURELIA** study is the first Phase III study to evaluate the efficacy and safety profile of Avastin when added to chemotherapy in women with previously treated (recurrent) platinum-resistant ovarian cancer. Avastin is approved for women with newly diagnosed advanced ovarian cancer in Europe.

AURELIA: A randomized Phase III trial evaluating bevacizumab (BEV) plus chemotherapy (CT) for platinum (PT)-resistant recurrent ovarian cancer (OC). Abstract #LBA5002. ASCO press briefing Friday, June 1. Oral presentation, Saturday, June 2, 3:30 PM – 3:45 PM CDT in E354b.

Updated overall survival data on Zelboraf for people with metastatic melanoma

Updated OS data will be shared for Zelboraf, the first and only approved personalized skin cancer medicine for patients with BRAF V600E mutation-positive unresectable or metastatic melanoma

BRIM3: Updated overall survival (OS) results for BRIM3, a Phase III randomized, open-label, multicenter trial comparing BRAF inhibitor vemurafenib (vem) with dacarbazine (DTIC) in previously untreated patients with BRAF V600E mutated melanoma. Abstract #8502. Oral presentation, Monday, June 4, 8:30 – 8:45am, CDT in E Arie Crown Theater.

Full session details of the 2012 Annual Meeting can be found through the [ASCO ePlanner](#).

About trastuzumab emtansine

Trastuzumab emtansine (T-DM1) is an investigational antibody-drug conjugate (ADC) being studied in HER2-positive cancers. Trastuzumab emtansine is designed to inhibit HER2 signaling and deliver the chemotherapy agent DM1 directly inside HER2-positive cancer cells. Trastuzumab emtansine offers both the potential benefits of trastuzumab and the unique targeted delivery of chemotherapy, which may result in improved efficacy and fewer adverse events. Trastuzumab emtansine binds to HER2-positive cancer cells and is thought to block out-of-control signals that make the cancer grow while also calling on the body’s immune system to attack the cancer cells. Once trastuzumab emtansine is absorbed into those cancer cells, it is designed to destroy them by releasing the DM1. Building on the results of trastuzumab emtansine studies to date, Roche and Genentech have approximately 30 ADCs in the pipeline.

Genentech licenses technology for trastuzumab emtansine under an agreement with ImmunoGen, Inc.

About Avastin: Over 7 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 Europe for the treatment of advanced stages of breast cancer, colorectal cancer, non-small cell lung cancer, kidney cancer and ovarian cancer, and is available in the US for the treatment of colorectal cancer, non-small cell lung cancer and kidney cancer. In addition, Avastin is approved in the US and over 30 other countries for the treatment of patients with glioblastoma (a type of brain cancer). Avastin is approved in Japan for the treatment of the advanced stages of colorectal, non-small cell lung

cancer and breast 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 one 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 tumour types.

About Zelboraf

Zelboraf is a prescription medicine that is an oral, small molecule, kinase inhibitor indicated for the monotherapy treatment of adult patients with BRAF V600 mutation positive unresectable or metastatic melanoma. Zelboraf is not recommended for use in melanoma patients with wild-type BRAF. Zelboraf is being co-developed under a 2006 license and collaboration agreement between Roche and Plexxikon, a member of the Daiichi Sankyo Group.

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 personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 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.

All trademarks used or mentioned in this release are protected by law.

Services

- [Send E-Mail](#)
- [IR Team](#)
- [RSS-Feeds](#)
- [Roche Events Podcast](#)
- [Subscribe to IR News](#)
- [Follow Roche on Twitter](#)
- [Roche Finance Info System](#)

Additional information

- [Roche in Oncology](#)