

Basel, 15 May 2009

## **Roche to present major advances with targeted cancer medicines at ASCO**

**More than 500 scientific abstracts to be presented across 20 types of cancers. Results could significantly improve the way cancer is treated for patients with inoperable stomach cancer; advanced melanoma; lung and breast cancers.**

Roche today provided an overview of results from studies that further the company's approach to developing targeted medicines for people with cancer, a diagnosis that will affect more than one in three people during their lifetime. Results from studies involving the company's approved and investigational treatments will be presented during the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO) taking place May 29 through June 2 in Orlando, USA.

- **Advances in HER2-targeted therapy:** Positive Phase III results for Herceptin in advanced HER2-positive stomach cancer and encouraging Phase II data in metastatic HER2-positive breast cancer with the novel treatment trastuzumab-DM1 (T-DM1) that uses the Herceptin antibody to deliver a specialised cancer cell-killing agent to tumour cells.
- **New approaches to treating lung cancer:** Positive Phase III studies of Avastin and Tarceva as first-line maintenance treatments in advanced non-small cell lung cancer (NSCLC), including important information about biomarkers in lung cancer.
- **Avastin in early-stage colon cancer:** Full results on the first Phase III study (C-08).
- **Personalising cancer treatment:** encouraging early data for Roche's targeted BRAF inhibitor in malignant melanoma.
- **Combined Roche and Genentech oncology pipeline:** includes 27 investigational agents in clinical studies.

William M. Burns, CEO of Roche's Pharmaceuticals Division: "We are presenting strong data for our targeted medicines for difficult-to-treat cancers including inoperable stomach cancer, lung cancer and melanoma. Data on Herceptin will show that it is a very effective treatment in patients with HER2-positive gastric cancer where current therapies are associated with poor survival and toxicity." Burns added: "We will also show very encouraging early data on a new, highly selective drug for malignant melanoma, the most serious type of skin cancer for which there are few treatments and no established standard of care."

### **Targeted therapy with Herceptin prolongs lives of patients with HER2-positive advanced stomach cancer**

Results from the pivotal ToGA study will demonstrate unprecedented benefits associated with the targeted therapy Herceptin (trastuzumab) in helping patients with inoperable stomach cancer live longer, similar to the proven survival benefit of Herceptin observed in HER2-positive breast cancer. Results from the ToGA study which investigated the use of Herceptin in combination with chemotherapy (Xeloda [capecitabine] /intravenous 5-FU and cisplatin) will show how biomarker guided therapy could change the treatment of this devastating disease. Every year one million people worldwide are diagnosed with stomach cancer and 800,000 people die. Link to ASCO abstract LBA4509: [www.abstract.asco.org](http://www.abstract.asco.org).

### **New combination approach to attack HER2-positive breast cancer**

Final efficacy results will be presented from a Phase II study (TDM4258g) of T-DM1 in women whose breast cancer had progressed following previous treatment with two or more HER2-targeted therapies. These patients who have nearly no treatment options left, still could benefit from T-DM1. T-DM1 is a novel antibody-drug combination that links Herceptin and the cell-killing agent DM1. A Phase III study (EMILIA) evaluating T-DM1 for second-line advanced HER2-positive breast cancer was initiated this year.

### **Chemo-free targeted maintenance treatment for lung cancer**

Two pivotal Phase III studies will show that effective maintenance treatment can help lung cancer patients continue to fight their disease without the need for continued chemotherapy, potentially creating a new treatment strategy in lung cancer. The first of the studies (SATURN) demonstrates the benefits of the targeted agent Tarceva (erlotinib) in helping patients with NSCLC live longer without their disease progressing when given after chemotherapy. The second study (ATLAS) will highlight efficacy data in patients treated with Avastin (bevacizumab) followed by combined maintenance treatment with Avastin and Tarceva.

### **First trial results of Avastin in the adjuvant setting**

Full results from the first trial of Avastin in early-stage colon cancer (known as NSABP C-08) will be presented. Although the study did not meet its primary endpoint of improving disease free survival, initial review of the data suggests Avastin may be active in patients with early-stage colon cancer. The ongoing adjuvant program in colon, breast and lung cancer involves over 26,000 patients. This includes the AVANT trial in early-stage colon cancer, results of which are expected in 2010. These results also do not impact Avastin's approved use in advanced or metastatic colorectal cancer.

### **Continuing proof in metastatic colorectal cancer**

A number of significant data presentations will be made at ASCO which confirm Avastin-based therapy as the standard of care in metastatic colorectal cancer with proven efficacy in all patient sub-groups. These will also highlight the extensive ongoing research program which will help unlock Avastin's full potential across all stages of the disease.

CO-8 and ATLAS are two of 10 oral presentations on Avastin at the meeting. Results will be presented for mid-stage studies in other types of cancer as well. Avastin is being studied in more than 450 clinical studies worldwide and more than 30 different tumour types.

### **Potential new personalised treatment for malignant melanoma**

Roche and its partner, Plexxikon Inc., will present promising results from a Phase I trial of PLX4032/R7204. This is a highly selective medicine that targets the mutated cancer-causing *BRAF* protein that occurs in 60% of melanoma (skin) cancers and up to eight percent of all solid tumours. Based on the significant responses seen in the phase I study, the medicine could enter registration trials for malignant melanoma later this year. Melanoma is an aggressive cancer for which few treatment options are currently available. If successful in treating melanoma PLX4032 is expected to be launched with a companion diagnostic, also being co-developed by Roche and Plexxikon which would be another step forward in personalising this cancer treatment. Link to ASCO abstract #9000 on-line: [www.abstract.asco.org](http://www.abstract.asco.org).

The 2009 ASCO Annual Meeting takes place from 29 May to 2 June, Orlando, Florida, USA. Full details can be found at <http://www.asco.org/ASCO/Meetings/ASCO+Annual+Meeting>.

Full details of key Roche data presentations will be given on Friday 29 May at an invitation-only media event for non-USA journalists. If you or your media colleagues are interested in attending this event please contact Roche Group Media Relations.

### **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 2008, Roche had over 80'000 employees worldwide and invested almost 9 billion Swiss francs in R&D.

The Group posted sales of 45.6 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:

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### **Additional information**

- More about Roche's work in oncology: [www.roche.com/media\\_backgrounder/media\\_oncology.htm](http://www.roche.com/media_backgrounder/media_oncology.htm)
- Oncology backgrounders: [www.roche.com/media\\_backgrounder/media\\_oncology.htm](http://www.roche.com/media_backgrounder/media_oncology.htm)
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- [www.thenewsmarket.com](http://www.thenewsmarket.com)
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