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Roche

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Data show greater understanding of disease pathways and personalising treatments for people with cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that encouraging data on its investigational and approved medicines will be presented at the 2011 European Multidisciplinary Cancer Congress in Stockholm being held 23-27 September 2011. Presentations include important new data on Roche's investigational antibody-drug conjugate trastuzumab emtansine (T-DM1) in HER2-positive metastatic breast cancer and pivotal data on vismodegib an investigational oral drug that targets a specific disease pathway in advanced skin cancer.

"Our data at this congress demonstrate our long-term commitment to understanding and targeting cancer pathways and personalising medicines," remarked Hal Barron, M.D., Chief Medical Officer and head, Global Product Development. "These advances in incurable diseases encourage us to continue to develop new and better medicines for people with cancer.''

Key study results to be presented include:

- **Trastuzumab emtansine**: Data from a Phase II study comparing trastuzumab emtansine to Herceptin plus chemotherapy in people with previously untreated HER2-positive metastatic breast cancer will be presented. Trastuzumab emtansine is an investigational medicine known as an antibody-drug conjugate (ADC). This is the first time progression-free survival data from a randomised study of trastuzumab emtansine will be presented. These results have been selected to be part of the official congress press program.
- **Vismodegib**: Results from the pivotal ERIVANCE BCC study in patients with an advanced form of a specific skin cancer called basal cell carcinoma (BCC) will be presented. The primary endpoint of the study was overall response

rate (tumour shrinkage and healing of visible lesions). These data will be highlighted as the best abstract during the 1st Presidential Symposium at the congress on Saturday afternoon.

- **Avastin in lung cancer**: Data from a new Phase III trial (AVAPERL) evaluating Avastin in combination with pemetrexed chemotherapy in advanced non-small cell lung cancer (NSCLC) will be presented for the first time. The study measured how long patients lived without their disease progressing (PFS) as primary endpoint.
- **Zelboraf (vemurafenib)**: Updated data from Phase I and III (BRIM3) studies of Zelboraf in BRAF V600E-mutation positive metastatic melanoma will be presented. New top-line Phase I results will feature longer-term overall survival data, including the two-year survival rate.
- **Avastin (bevacizumab) biomarker**: An extensive search for a biomarker aiming to predict which people may derive more benefit from Avastin therapy has been ongoing for more than a decade. Over 100 candidate markers have been assessed in more than 20 Phase III Avastin clinical trials across 7 cancer types. VEGF-A has emerged as a leading candidate from preliminary data in certain cancers and this is being further evaluated. Data relating to VEGF-A will be presented in several indications including advanced breast, pancreatic and lung cancer, as well as data from other candidates within the ongoing biomarker programme.

Key abstract information:

- **Trastuzumab emtansine (T-DM1)**
  Trastuzumab emtansine (T-DM1) vs. trastuzumab plus docetaxel (H+T) in previously-untreated HER2-positive metastatic breast cancer (MBC): primary results of a randomised, multicentre, open-label Phase II Study (TDM4450g/BO21976) (Abstract #5001). Congress press briefing, Saturday 24 September, 08:00 CET, embargoed to Sunday 25 September, 00:01 CET; Breast Cancer, Early & Advanced Disease oral presentation, Sunday 25 September, 09:10 CET, Hall A1.
- **Vismodegib**
  BEST ABSTRACT: A pivotal multicentre trial evaluating efficacy and safety of the Hedgehog pathway inhibitor (HPI) vismodegib in patients with advanced basal cell carcinoma (BCC) (Abstract #1BA). Presidential Session I: Best and Late Breaking Abstracts, Saturday 24 September, 14:15 CET, Hall A1.
- **Zelboraf (vemurafenib)**
  LATE BREAKING ABSTRACT: Vemurafenib improves overall survival compared to dacarbazine in advanced BRAFV600E-mutated melanoma: updated survival results from a Phase III randomised, open-label, multicentre trial (Abstract #28LBA). Melanoma and Skin Cancer oral presentation, Saturday 24 September, 13:00 CET, Hall T1.
- **Avastin Avaperl**
  LATE BREAKING ABSTRACT: AVAPERL (MO22089): Final efficacy outcomes for patients (pts) with advanced non-squamous non-small cell lung cancer (nsNSCLC) randomised to continuation maintenance (mtc) with bevacizumab (bev) or bev+pemetrexed (pem) after first-line (1L) bev-cisplatin (cis)-pem treatment (Tx) (Abstract #34LBA). Lung Cancer- Early

and Metastatic oral presentation, Saturday 24 September, 13:45 CET, Hall C5.

- **Key Avastin biomarker abstract**
  Evaluation of plasma VEGFA as a potential predictive pan-tumour biomarker for bevacizumab (Abstract #804). Personalized Medicine oral presentation, Sunday 25 September, 09:55 CET, Victoria Hall.

About trastuzumab emtansine

Trastuzumab emtansine (the International Non-proprietary Name for T-DM1) is an antibody-drug conjugate (ADC) being studied for HER2-positive metastatic breast cancer. It is designed to inhibit HER2 signaling and deliver the chemotherapy DM1 directly inside HER2-positive cancer cells. The antibody (trastuzumab) binds to the 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. Trastuzumab emtansine attaches trastuzumab and DM1 together using a stable linker which is designed to keep trastuzumab emtansine in one piece until it reaches specific cancer cells.

About vismodegib

Vismodegib is an investigational oral medicine designed to target the underlying molecular driver of basal cell carcinoma. Abnormal signaling in a cell growth pathway known as the Hedgehog pathway is implicated in more than 90 percent of BCC cases and vismodegib is designed to selectively inhibit abnormal signaling in the Hedgehog pathway. Patients with advanced basal cell carcinoma (aBCC) have lesions which are either metastatic or locally advanced and for whom surgery is considered inappropriate.

About Zelboraf

Zelboraf is an oral, small molecule, kinase inhibitor designed to selectively inhibit a cancer-driving mutated form of the BRAF protein. It was approved by the US Food and Drug Administration (FDA) in August 2011 together with the cobas 4800 BRAF V600 Mutation Test companion diagnostic test for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation. Zelboraf is not recommended for use in melanoma patients who lack the BRAF V600E mutation. Roche has also submitted new drug applications for Zelboraf in the EU, Switzerland, Australia, New Zealand, Brazil, India, Mexico and Canada. While Roche seeks regulatory approval of Zelboraf in other countries, a global Expanded Access Program (EAP) is available for people with previously treated or untreated BRAF V600 mutation-positive metastatic melanoma.

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 32 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 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 (including colorectal, breast, non-small cell lung, brain, gastric, ovarian and others) and different settings (advanced or early stage disease).

SOURCE [1]

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Links:
[1] http://www.roche.com/media/media_releases/med-cor-2011-09-19.htm