# ESMO 2012: Roche underscores leadership in oncology with new data in HER2 positive breast cancer and skin cancer

Roche

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Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that data on thirteen of its investigational and approved products will be presented at the European Society for Medical Oncology (ESMO) Congress taking place in Vienna, Austria on 28 September - 2 October 2012.

During the past 50 years Roche has developed and secured approval for ten cancer medicines. The data presented at ESMO 2012 reflect not only the continuing role being played by Roche’s early discoveries, but also the potential of the company’s newer treatments. Highlights will include data on personalised medicines from the company’s HER2 and skin cancer franchises.

"Our mission is to develop therapies that transform medicine," said Hal Barron M.D., Chief Medical Officer and Head, Global Product Development. "The improvement in survival with trastuzumab emtansine (T-DM1) and other data presented at ESMO reflect our commitment to make a real difference for people living with cancer."

## HER2-positive breast cancer

Since it was first licensed in 1998, Herceptin has become the foundation of care in HER2-positive breast cancer. Data presented at ESMO 2012 will reflect both the pivotal role Herceptin continues to play, but also highlights how decades of research into HER2-positive cancer is enabling Roche to lead the next wave of developments that may further improve the treatment and outcomes for women with this aggressive disease:

- Further results including overall survival data will be presented from the Phase III EMILIA study. The trial compared trastuzumab emtansine (T-DM1) to Xeloda plus lapatinib in patients with HER2-positive unresectable locally advanced or metastatic breast cancer who had previously been treated with Herceptin and a taxane chemotherapy.
- Roche and the Breast International Group (BIG) will present the final analysis of the 5,000 patient, Phase III HERA (HERceptin Adjuvant) study. The study assessed how adjuvant treatment with Herceptin has impacted the disease

free survival (DFS; the time lived without return of the disease) of women with HER2-positive early breast cancer after completion of standard chemotherapy. Data will be presented comparing the DFS of women given Herceptin treatment for two years compared to those treated with Herceptin for one year. In addition, an update will be provided on Herceptin given for one year versus observation after eight years of follow-up.

Results from the PHARE study (run by the French National Cancer Institute), investigating six months versus one year of Herceptin treatment, will also be presented.

## Skin cancer

In the past, patients with metastatic melanoma could expect to live for as little as six to nine months after diagnosis. Today, treatments such as Zelboraf (vemurafenib) are helping to stall the growth or spread of the cancer and are enabling patients to survive longer, for the first time extending life expectancy beyond one year for many patients. Despite this progress, more still needs to be done to improve outcomes and to ensure that patients have treatment options at all stages of the disease:

- At ESMO 2012, results from a pilot study of 24 patients with BRAF V600 mutation-positive metastatic melanoma and symptomatic brain metastases who were treated with Zelboraf will be presented.
- Roche is building on its extensive clinical experience with Zelboraf to investigate a number of combination approaches, which may in the future expand the treatment options available to patients with this incurable disease. At ESMO 2012 the first results from BRIM7, a Phase Ib dose ranging study assessing the potential of combining Zelboraf with the MEK inhibitor GDC-0973 will be presented. Roche will further study the combination of Zelboraf and the MEK inhibitor GDC-0973 in a Phase III clinical investigation.

## Key abstract information:

- Pre-planned, final analysis of the Phase III HERceptin Adjuvant (HERA) trial (two years versus one year of treatment with Herceptin) (Abstract # LBA6_PR). [Monday 1 October. Hall A, 16.15].
- Updated Overall Survival 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) (Abstract #LBA 12). [Monday 1 October 2012. Hall A, 14.10].
- Phase IB Study of vemurafenib in combination with the MEK inhibitor, GDC-0973, in patients with locally advanced/unresectable or metastatic BRAFV600 mutation positive melanoma. (Abstract # LBA28). [Saturday 29 September. Hall C, 09:30].
- Open-label pilot study of vemurafenib in previously treated metastatic melanoma (mM) patients (pts) with symptomatic brain metastases (BM).

(Abstract #1125P). [Monday 1 October. Hall XL, 13:00].

## About Herceptin

Herceptin (trastuzumab) is a humanised monoclonal antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential when it is overexpressed. The mode of action of Herceptin is unique in that it activates the body’s immune system and suppresses HER2 signalling to target and destroy the tumour. Herceptin has demonstrated unprecedented efficacy in treating both early and advanced (metastatic) HER2-positive breast cancer. Given on its own as monotherapy as well as in combination with or following standard chemotherapy or following surgery, Herceptin has been shown to improve overall survival, response rates and disease-free survival while maintaining quality of life in women with HER2-positive breast cancer.

A subcutaneous (SC) formulation of Herceptin, administered as a five minute injection under the skin, is currently being investigated. An application for Herceptin SC (vial) formulation has been submitted to some Regulatory Authorities, including EMA and Swissmedic, and is currently under assessment.

Herceptin is marketed in the United States by Genentech, in Japan by Chugai and internationally by Roche. Since 1998, Herceptin has been used to treat more than 1.2 million people with HER2-positive breast cancer worldwide.

## About trastuzumab emtansine

Trastuzumab emtansine (T-DM1) is an antibody-drug conjugate (ADC) being studied in HER2-positive cancers. It is comprised of the antibody trastuzumab and the chemotherapy agent DM1 attached together using a stable linker. Trastuzumab emtansine is designed to target and inhibit HER2 signalling, and to deliver the chemotherapy agent DM1 directly inside HER2-positive cancer cells. Trastuzumab emtansine 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.

## About Zelboraf®

Zelboraf is a personalised oral medicine designed to specifically inhibit the activity of the mutant BRAF protein. It is the first and only approved BRAF inhibitor and has been proven to help patients with BRAF V600 mutation-positive metastatic melanoma in two important ways; it stalls the growth or spread of the cancer (PFS) and helps patients survive longer (OS), for the first time extending life expectancy beyond one year for many patients.

Clinical experience with Zelboraf is growing every day; it is already approved in 40 countries and has been used for the treatment of more than 7000 BRAF V600

mutation-positive metastatic melanoma patients worldwide.

To further enhance the potential treatment options available to patients at all stages of the disease, Roche is building on its extensive clinical experience with Zelboraf to investigate a number of combination approaches, including Zelboraf with the MEK inhibitor GDC-0973 and Zelboraf with immunotherapies.

Zelboraf was co-developed under a 2006 license and collaboration agreement between Roche and Plexxikon, now a member of the Daiichi Sankyo Group.

GDC-0973 [XL518] is a potent, highly selective inhibitor of MEK, a serine/threonine kinase that is a component of the RAS/RAF/MEK/ERK pathway. GDC-0973 is being developed by Genentech, a member of the Roche Group, under a collaboration agreement with Exelixis.

SOURCE [1]

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**Links:**
[1] http://www.roche.com/media/media_releases/med-cor-2012-09-24.htm