

# Exhibit 3

Roche - Investor Update



Investor Update

Basel, 15 December 2006

**Herceptin provides proven survival benefit in advanced breast cancer and the best chance of a cure in early breast cancer**

Compelling new evidence for Herceptin as the foundation of care in HER2-positive breast cancer presented at San Antonio Breast Cancer Symposium

SAN ANTONIO, USA, 15th December 2006 – Compelling new data confirming the survival benefits of Herceptin (trastuzumab) in early and advanced HER2-positive breast cancer were presented at the San Antonio Breast Cancer Symposium (SABCS).

**Efficacy in Early Breast Cancer**

BCIRG 006

Updated results of the BCIRG 006 study<sup>1</sup> showed that adding Herceptin to either of two adjuvant chemotherapy regimens reduced the risk of death by 34 to 41% compared with chemotherapy alone. Furthermore, the addition of Herceptin significantly reduced the risk of cancer coming back by 33-39%. These remarkable data confirm the survival benefit provided by Herceptin to women with HER2-positive early breast cancer, as previously seen in three other large adjuvant Herceptin studies<sup>2,3</sup>.

**Efficacy in Advanced (Metastatic) Breast Cancer**

Hermine

An observational cohort study investigated a large patient pool (623 patients) treated with Herceptin-based therapy under real-life conditions.<sup>4</sup> Continuing Herceptin treatment after disease progression is associated with a marked survival advantage for patients with advanced stages of HER2-positive breast cancer:

- The median overall survival was 16.8 months for the group who did not continue Herceptin. For the group who received Herceptin after disease progression, the median overall survival had not yet been reached at 27.8 months
- Overall survival at 2 years was greater than 70% for those who continued Herceptin treatment after disease progression compared with less than 25% for those who did not

**CHAT**

The addition of Xeloda (capecitabine) to Herceptin and Taxotere (docetaxel) as first-line therapy in patients with advanced HER2-positive disease increased the amount of time before their disease progressed<sup>5</sup>:

- Time to progression (the median amount of time from randomisation until tumour growth) increased significantly from 13.8 to 18.2 months
- Overall response rate (tumour shrinkage) was high in both arms, approximately 70%, without statistically significant difference
- At the time of the analysis, overall survival results were immature due to short follow-up. Follow-up of this study is ongoing and final data analysis is expected in 2007

### **M77001**

Herceptin plus docetaxel given upfront provided a long term survival benefit in patients with HER2-positive metastatic breast cancer versus docetaxel alone<sup>6</sup>:

- Long-term survival of more than 4 years which is uncommon in patients with HER2-positive advanced disease was twice as often in women receiving Herceptin plus docetaxel upfront (20 vs 10 patients)
- Patients treated with combination therapy survived, on average, at least 31.3 months compared with 22.7 months for patients on docetaxel alone

“These data confirm once again that Herceptin delivers compelling survival benefit in metastatic HER2-positive breast cancer and offers the best chance of a cure in early disease,” commented Dr. Kapil Dhingra, Vice President, Medical Science, Oncology, Roche. “Herceptin is the only approved targeted tool we have to fight this aggressive type of breast cancer.”

HER2 is a protein produced by a specific gene with cancer-causing potential.

Approximately 20-30 percent<sup>7</sup> of patients with breast cancer have tumours which strongly overexpress HER2. HER2-positive breast cancer is related to a poor overall prognosis with a faster time to relapse at all stages of the disease.

### **Notes to editors:**

All SABCS abstracts [can be viewed](#) searching by author or title.

### **About the study with abstract # 52 (BCIRG 006)**

The BCIRG trial is an independent randomised study designed to evaluate the use of two chemotherapies (docetaxel and carboplatin) when combined with Herceptin following initial adjuvant treatment with doxorubicin and cyclophosphamide (AC) chemotherapy for early-stage, HER2-positive breast cancer. The abstract presented at the 2006 San Antonio Breast Cancer Symposium refers to the 36-month median follow-up results from the second planned interim analysis of the study. The primary end point was disease-free survival. The secondary end points included overall survival and safety.

A total of 3,222 women with early-stage HER2-positive breast cancer (including both lymph node-positive and node-negative patients) were enrolled into the trial and randomly assigned to one of three arms:

Arm A: doxorubicin and cyclophosphamide (q3w x 4), followed by docetaxel (q3w x 4) (AC -> T)

Arm B: doxorubicin and cyclophosphamide (q3w x 4), followed by docetaxel

(q3w x 4) plus Herceptin (qw x 12), followed by Herceptin (q3w x 13) (AC -> TH)

Arm C: docetaxel (q3w x 6) plus carboplatin (AUC 6) plus Herceptin (qw x 18), followed by Herceptin (q3w x 11) (TCH)

#### **About the study with abstract # 2064 (Hermine)**

The Hermine study was an observational French cohort study of a large patient population by 102 oncologists. Women aged 18 years or over with metastatic breast cancer who had begun Herceptin treatment during 2002 were eligible. An analysis was performed comparing patients treated with Herceptin in the first-line setting who continued treatment with those who discontinued Herceptin-based treatment at disease progression.

Herceptin was continued beyond disease progression in 107 (60%; Group A) of patients, who continued to receive Herceptin weekly. Herceptin was discontinued before or at disease progression in 70 patients (40%; Group B).

#### **About the study with abstract # 2063 (CHAT)**

A total of 222 patients were randomised into the study: 112 received Xeloda plus Herceptin and Taxotere and 110 received Herceptin and Taxotere alone.

Herceptin was administered at a dose of 6 mg/kg every 3 weeks until disease progression (after an initial loading dose of 8 mg/kg). Taxotere was administered at a dose of 100mg/m<sup>2</sup> every 3 weeks with Herceptin alone, and 75mg/m<sup>2</sup> when Xeloda was added, until disease progression. Xeloda was administered at a dose of 950 mg/m<sup>2</sup> twice daily for the first 14 days of each 3-week cycle. Patients in the Herceptin and Taxotere alone arm of the study were given the option to cross over to receive Xeloda, following disease progression.

The CHAT study has an external Data Safety Monitoring Board (DSMB) that regularly reviews safety data. No unexpected safety concerns were raised by the DSMB, and the incidence of cardiac heart failure was low (one patient in each treatment arm).

#### **About the study with abstract # 2067 (M77001)**

188 patients were recruited into the study (M77001), 94 patients randomised to receive Herceptin plus Taxotere and 94 randomised to receive Taxotere alone. Two patients in the combination arm did not receive study drug and were excluded from the final analysis. Taxotere was scheduled at a dose of 100 mg/m<sup>2</sup> every 3 weeks for at least 6 cycles. Herceptin was administered in 2mg/kg weekly doses until disease progression (after an initial loading dose of 4mg/kg). Patients in the Taxotere arm of the study were given the option to cross over to receive Herceptin, following disease progression.

#### **About breast cancer**

Breast cancer is the most common cancer among women worldwide.<sup>8</sup> Each year more than one million new cases of breast cancer are diagnosed worldwide, and nearly 400,000 people will die of the disease annually.<sup>9</sup>

In HER2-positive breast cancer, increased quantities of the HER2 protein are present on the surface of the tumour cells. This is known as 'HER2-positivity.' High levels of HER2 are present in a particularly aggressive form of the disease which responds poorly to chemotherapy. Research shows that HER2-positivity

affects approximately 20-30 percent of women with breast cancer.

### **About Herceptin (trastuzumab)**

Herceptin is a humanised antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential. It has demonstrated efficacy in treating both early and advanced (metastatic) breast cancer. Given on its own as monotherapy as well as in combination with or following standard chemotherapy, Herceptin has been shown to improve response rates, disease-free survival and overall survival while maintaining quality of life in women with HER2-positive breast cancer.

Herceptin received approval for use in the European Union for advanced (metastatic) HER2-positive breast cancer in 2000 and for early HER2-positive breast cancer in 2006. In the advanced setting, Herceptin is now approved for use as a first-line therapy in combination with paclitaxel where anthracyclines are unsuitable, as first-line therapy in combination with docetaxel, and as a single agent in third-line therapy. In the early setting, Herceptin is approved for use following standard (adjuvant) chemotherapy. 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 over 310,000 HER2-positive breast cancer patients worldwide.

### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life.

Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2005 sales by the Pharmaceuticals Division totalled 27.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.2 billion Swiss francs. Roche employs roughly 70,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet ([www.roche.com](http://www.roche.com)).

All trademarks used or mentioned in this release are legally protected.

To access video clips, in broadcast standard, free of charge, please go to:  
[www.thenewsmarket.com](http://www.thenewsmarket.com)

1) Slamon D, et al. BCIRG 006: 2nd interim analysis phase III randomised trial comparing doxorubicin and cyclophosphamide followed by docetaxel (AC -> T) with doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab (AC -> TH) with docetaxel, carboplatin and trastuzumab (TCH) in HER2neu positive early breast cancer patients. Abstract # 52, San Antonio Breast Cancer Symposium 2006

2.) Piccart-Gebhart MJ et al. Trastuzumab after adjuvant chemotherapy in HER2-positive breast cancer. N Engl J Med. 2005 Oct 20;353(16):1659-72.

- 3) Romond, E., Perez, E. et al. Trastuzumab plus Adjuvant Chemotherapy for Operable HER2 Positive Breast Cancer. *New England Journal of Medicine* 353:16 2005
- 4) Extra J-M, et al. Favourable effect of continued trastuzumab treatment in metastatic breast cancer patients: results from the French Hermine cohort study. Abstract # 2064, San Antonio Breast Cancer Symposium 2006
- 5) Wardley A, et al. Trastuzumab plus docetaxel with or without capecitabine in patients with HER2-positive advanced / metastatic breast cancer: first efficacy results from the Phase II MO16419 (CHAT) study. Abstract # 2063, San Antonio Breast Cancer Symposium 2006
- 6) Marty M, et al. Superior long-term survival benefits of trastuzumab plus docetaxel compared to docetaxel alone in patients with HER2-positive metastatic breast cancer: patients surviving more than 4 years in the M77001 study. Abstract # 2067, San Antonio Breast Cancer Symposium 2006
- 7) Harries M, Smith I. The development and clinical use of trastuzumab (Herceptin). *Endocr Relat Cancer* 9: 75-85, 2002.
- 8) World Health Organization,  
<http://www.who.int/cancer/detection/breastcancer/en/>
- 9) Ferlay J, et al., GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No.5, Version 2.0. IARC Press, Lyon, 2004. 2004

© 2007 F. Hoffmann-La Roche Ltd

[print close](#)

This website contains information on products which is targeted to a wide range of audiences and could contain product details or information otherwise not accessible or valid in your country. Please be aware that we do not take any responsibility for accessing such information which may not comply with any valid legal process, regulation, registration or usage in the country of your origin.