

Basel, 18 March 2009

Herceptin now shown to significantly prolong the lives of patients with HER2-positive advanced stomach cancer

Targeted therapy set to change treatment paradigm in stomach cancer

Roche today announced results from a major international study which show that adding Herceptin (trastuzumab) to standard chemotherapy significantly prolongs lives of patients with HER2-positive stomach (gastric) cancer. The results are from ToGA, a large international Phase III trial investigating the benefit of Herceptin as the first therapy for patients with advanced and inoperable stomach cancer (first line). Full data will be presented at an upcoming medical meeting.ⁱ

"Stomach cancer is often incredibly hard to treat, as it is frequently diagnosed at a late stage" said principal investigator Prof. Eric Van Cutsem, University Hospital Gasthuisberg in Leuven, Belgium. "Based on the clear positive outcome from this clinical study, the addition of Herceptin to chemotherapy offers a new important option for patients with HER2-positive stomach cancer as Herceptin extends survival and will bring this group of patients a significant benefit."

Stomach cancer is the second most common cause of cancer-related death in the world with over 900,000 new cases diagnosed each year. Early diagnosis is difficult because most patients do not show symptoms in the early stage. Advanced stomach cancer is associated with a poor prognosis, the average time patients survive after diagnosis is approximately 10 months with currently available therapies.ⁱⁱ Approximately 22% of stomach tumours overexpress HER2.ⁱⁱⁱ

"Herceptin was a breakthrough treatment for patients with HER2-positive breast cancer and has become the foundation of care across all stages of HER2-positive breast cancer", said William M. Burns, CEO of Roche's Pharmaceuticals Division. "The ToGA study shows for the first time that Herceptin extends the lives of patients in a cancer other than breast cancer. Advanced stomach cancer is a devastating disease for which there are currently few treatment options. Consequently, the targeted therapy Herceptin will become an integral part of treatment for this type of cancer."

About the ToGA study

ToGA is the first randomised Phase III trial investigating the use of Herceptin in patients with inoperable locally advanced, recurrent and/or metastatic HER2-positive gastric cancer. Approximately 3,800 patients were tested for HER2-positive tumours and 594 patients with HER2-positive disease were enrolled into the study. The rationale for conducting this trial was based on the knowledge that the targeted therapy Herceptin has demonstrated unprecedented efficacy in the treatment of HER2-positive breast cancer. In addition, the overexpression of HER2 was also observed in stomach cancer. A targeted anti-cancer therapy is a type of medication that blocks the growth of cancer cells by interfering with specific molecules which cause a tumor to grow.

In the ToGA study, patients were randomised to receive one of the following regimens as their first line of treatment:

- A fluoropyrimidine (Xeloda or 5-FU) and cisplatin every 3 weeks for 6 cycles
- Herceptin 6mg/kg every 3 weeks until progression in combination with a fluoropyrimidine and cisplatin for 6 cycles

The primary objective of the study was to demonstrate superiority in overall survival of the Herceptin-containing treatment arm compared to the chemotherapy alone arm. The pre-planned interim analysis was triggered by the occurrence of 347 events. Secondary endpoints for the study included progression-free survival, overall response rate, duration of response, safety and quality of life. In the ToGA study, no new or unexpected side effects were observed.

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. The mode of action of Herceptin is unique in that it activates the body's immune system and suppresses HER2 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, 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. It is also approved for use in combination with an aromatase inhibitor for the treatment of post-menopausal patients with HER2 and hormone receptor co-positive metastatic breast cancer. In the early setting, Herceptin is approved for use following standard (adjuvant) chemotherapy.

Herceptin is currently being evaluated for treatment of HER2-positive stomach cancer through an extensive international clinical trial programme.

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 nearly 600,000 patients with HER2-positive breast cancer 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 the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, and is a market leader in virology. It is also active in other major therapeutic areas such as autoimmune diseases, inflammatory and metabolic disorders and diseases of the central nervous system. In 2008 sales by the Pharmaceuticals Division totalled 36.0 billion Swiss francs, and the Diagnostics Division posted sales of 9.7 billion francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invested nearly 9 billion Swiss francs in R&D in 2008. Worldwide, the Group employs about 80,000 people. Additional information is available on the Internet at www.roche.com.

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

To access video clips, of broadcast standard, free of charge, please go to: www.thenewsmarket.com.

Roche Group Media Office

Phone: +41 61 688 8888 / Email: basel.mediaoffice@roche.com

- Daniel Piller (Head)

- Alexander Klauser

- Valeria Passoni
- Martina Rupp
- Claudia Schmitt

References

- ⁱ TBC ASCO 2009
- ⁱⁱ Ohtsu A. J Gastroenterol 2008;43:256-264
- ⁱⁱⁱ Bang YJ et al. ASCO 2008 (poster no. 4526)