Media Release

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Roche's trastuzumab emtansine (T-DM1) showed positive Phase III results in HER2-positive metastatic breast cancer

EMILIA study showed trastuzumab emtansine significantly extended the time people with HER2-positive metastatic breast cancer lived without their disease getting worse

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced topline results of EMILIA, the first randomised Phase III study of trastuzumab emtansine (T-DM1). The study enrolled people with HER2-positive metastatic breast cancer (mBC) who had previously received treatment with Herceptin® and a taxane (chemotherapy). The study showed people who received trastuzumab emtansine lived significantly longer without their disease getting worse (progression-free survival, PFS) compared to those who received lapatinib plus Xeloda (capecitabine). Final results for overall survival (OS), a co-primary efficacy endpoint of EMILIA, are not yet mature. The safety profile of trastuzumab emtansine was consistent with that seen in previous studies. These data will be submitted for presentation at an upcoming medical meeting.

Trastuzumab emtansine is an investigational medicine known as an antibody-drug conjugate (ADC). It is comprised of the antibody trastuzumab and the chemotherapy agent DM1 attached together using a stable linker. It is designed to target and inhibit HER2 signaling and deliver the chemotherapy directly inside HER2-positive cancer cells. Trastuzumab emtansine reinforces Roche's personalized healthcare approach of developing targeted medicines to fight cancer.

"Trastuzumab emtansine represents a new approach for the treatment of patients with HER2-positive breast cancer that comes from our decades of research on the HER pathway," said Hal Barron, M.D., Chief Medical Officer and Head, Global Product Development. "We are excited about the EMILIA results because trastuzumab emtansine is our first antibody drug conjugate and it may help people who still need more treatment options for this aggressive disease. We will work to submit these data to regulatory authorities as quickly as possible."

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Based on these findings, Roche plans to submit a Marketing Authorisation Application to the European Medicines Agency (EMA) this year for trastuzumab emtansine in HER2-positive mBC. In addition, Genentech plans to submit a Biologics License Application for trastuzumab emtansine to the U.S. Food and Drug Administration (FDA) this year for the same indication.

About the EMILIA study

EMILIA (TDM4370g/BO21977) is an international, Phase III, randomised, open-label study comparing trastuzumab emtansine alone to lapatinib in combination with Xeloda in 991 people with HER2-positive mBC whose disease progressed after initial treatment with Herceptin and a taxane-based chemotherapy.

Participants in the trastuzumab emtansine arm received:

- Trastuzumab emtansine 3.6 mg/kg every three weeks

Participants in the lapatinib and Xeloda arm received:

- Lapatinib 1250 mg daily
- Xeloda 2000 mg/m^2, days 1 – 14, every three weeks

The co-primary efficacy endpoints of the study are PFS (as assessed by an independent review committee) and OS. Other study endpoints include safety profile, one-year and two-year survival rates, PFS as assessed by investigator, overall response rate, duration of response and quality of life.

About trastuzumab emtansine

Trastuzumab emtansine (T-DM1) is an ADC being studied in HER2-positive cancers. Trastuzumab emtansine is designed to inhibit HER2 signaling and deliver the chemotherapy agent DM1 directly inside HER2-positive cancer cells. Trastuzmab emtansine offers both the potential benefits of trastuzumab and the unique targeted delivery of chemotherapy, which may result in improved efficacy and fewer adverse events. 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.

In addition to EMILIA, there are two ongoing Phase III studies of trastuzumab emtansine:

- MARIANNE is comparing three different regimens (trastuzumab emtansine alone, trastuzumab emtansine plus pertuzumab, and Herceptin plus a taxane chemotherapy) in people with HER2-positive mBC who have not been previously treated for their metastatic disease.
- TH3RESA is comparing trastuzumab emtansine with physician's choice of treatment in people with HER2-positive metastatic breast cancer who have already received both Herceptin and lapatinib.

Genentech, a member of the Roche Group, licenses technology for trastuzumab emtansine under an agreement with ImmunoGen, Inc.

Building on the results of trastuzumab emtansine studies to date, Roche/Genentech have approximately 30 ADCs in the pipeline.

About breast cancer

Breast cancer is the most common cancer among women worldwide.[i] Each year about 1.4 million new cases of breast cancer are diagnosed worldwide, and over 450,000 women will die of the disease annually.[1] In HER2-positive breast cancer, increased quantities of the human epidermal growth factor receptor 2 (HER2) are present on the surface of the tumour cells. This is known as “HER2 positivity” and affects approximately 15-20 percent of women with breast cancer.[ii] HER2-positive cancer is a particularly aggressive form of breast cancer.[iii]

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 personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2011, Roche had over 80,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 42.5 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: www.roche.com.

Additional information

- Roche in Oncology: www.roche.com/de/media/media_backgrounder/media_oncology.htm

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