Roche & #039;s trastuzumab emtansine (T-DM1) significantly extended survival in people with aggressive form of breast cancer

Roche

Basel, 1 October 2012

Roche’s trastuzumab emtansine (T-DM1) significantly extended survival in people with aggressive form of breast cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced updated survival results from the Phase III EMILIA study, which showed that people with previously treated HER2-positive metastatic breast cancer (mBC) survived significantly longer (overall survival, a co-primary endpoint) when treated with trastuzumab emtansine (T-DM1) compared to those who received the combination of lapatinib and Xeloda (capecitabine).

Results showed the risk of death was reduced by 32 percent for people who received trastuzumab emtansine compared to those who received lapatinib plus Xeloda (HR=0.68; P=0.0006). People in the study treated with trastuzumab emtansine survived a median of 5.8 months longer than those who received lapatinib and Xeloda (median overall survival: 30.9 months vs. 25.1 months). No new safety signals were observed and adverse events (AEs) were consistent with those seen in previous studies, with fewer people who received trastuzumab emtansine experiencing Grade 3 or higher (severe) (AEs) than those who received lapatinib plus Xeloda (40.8 percent vs. 57.0 percent).[1]

"We are extremely pleased that the new data from the EMILIA study showed people receiving trastuzumab emtansine survived longer than those who received the standard of care," said Hal Barron, M.D., Chief Medical Officer and Head, Global Product Development. “We are continuing to work with regulatory authorities to bring this innovative medicine, which significantly improved both progression-free survival and overall survival, to people with HER2-positive metastatic breast cancer as soon as possible.”

These updated survival results from the EMILIA study will be presented at the ESMO 2012 Congress (European Society for Medical Oncology) (Abstract # LBA12, Monday, October 1, 2012, 14.10 CEST) by Dr. Sunil Verma, Sunnybrook Regional Cancer Center, University of Toronto, Canada. Data from the EMILIA study has also been published today in the online edition of the New England Journal of Medicine.[2]

Genentech, a member of the Roche Group, has submitted a Biologics License Application (BLA) for trastuzumab emtansine to the U.S. Food and Drug Administration (FDA) for use in people with HER2-positive, unresectable locally advanced or metastatic breast cancer. Roche has submitted a Marketing

Authorisation Application to the European Medicines Agency (EMA) for the same indication.

Based on these updated overall survival results, people in the lapatinib and Xeloda arm of EMILIA are being offered the option to receive trastuzumab emtansine.

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 locally advanced or metastatic breast cancer who had previously been treated with Herceptin and a taxane chemotherapy.

The study has met both co-primary efficacy endpoints of progression free survival (PFS, as assessed by an independent review committee) and overall survival. PFS and safety results from the EMILIA study were previously reported at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2012 and include:

- A significant improvement in the time people receiving trastuzumab emtansine (n=495) lived without their disease getting worse (PFS) compared to those who received lapatinib plus Xeloda (n=496), as assessed by independent review (HR=0.65, 35 percent reduction in risk of disease worsening or death, p