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Roche

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New personalised medicine helped people in Phase III study live longer, compared to standard treatment

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved Kadcyla (trastuzumab emtansine or T-DM1) for the treatment of people with HER2-positive metastatic breast cancer (mBC) who have received prior treatment with Herceptin (trastuzumab) and a taxane chemotherapy. Kadcyla is the fourth medicine from Roche to receive FDA approval for people with advanced cancers within the past two years.

An antibody-drug conjugate (ADC) is a new kind of targeted cancer medicine that can attach to certain types of cancer cells and deliver chemotherapy directly to them. Kadcyla is the first FDA-approved ADC for treating HER2-positive mBC, an aggressive form of the disease.

“Kadcyla is an antibody-drug conjugate representing a completely new way to treat HER2-positive metastatic breast cancer, and it helped people in the EMILIA study live nearly six months longer,” said Hal Barron, M.D., Roche’s Chief Medical Officer and Head, Global Product Development. “We currently have more than 25 antibody-drug conjugates in our pipeline and hope this promising approach will help us deliver more medicines to fight other cancers in the future.”

Kadcyla is made up of the antibody, trastuzumab, and the chemotherapy, DM1, joined together using a stable linker. Kadcyla combines the mechanisms of action of both trastuzumab and DM1, and it is the first Roche ADC approved by the FDA. Roche has studied ADC science for more than a decade and has eight ADCs in Phase I or Phase II studies for different types of cancer.

Roche has also submitted a Marketing Authorisation Application to other Regulatory Authorities around the world, including the European Medicines Agency (EMA), for Kadcyla for the treatment of people with HER2-positive mBC. This application is

currently under review by the EMA.

Kadcyla efficacy in HER2-positive mBC

The FDA approval of Kadcyla is based on results from EMILIA (TDM4370g/BO21977), an international, Phase III, randomised, open-label study comparing Kadcyla alone to lapatinib in combination with Xeloda (capecitabine) in 991 people with HER2-positive locally advanced breast cancer or mBC who had previously been treated with Herceptin and a taxane chemotherapy. Results include:[1]

- The study met both co-primary efficacy endpoints of overall survival and progression-free survival (PFS; as assessed by an independent review committee).
- People who received Kadcyla lived a median of 5.8 months longer (overall survival) than those who received the combination of lapatinib and Xeloda, the standard of care in this setting (median overall survival: 30.9 months vs. 25.1 months).
- People receiving Kadcyla experienced a 32 percent reduction in the risk of dying compared to people who received lapatinib and Xeloda (HR=0.68; p=0.0006).
- People who received Kadcyla lived significantly longer without their disease getting worse (PFS) compared to those who received lapatinib plus Xeloda (HR=0.65, 35 percent reduction in the risk of disease worsening or death, p