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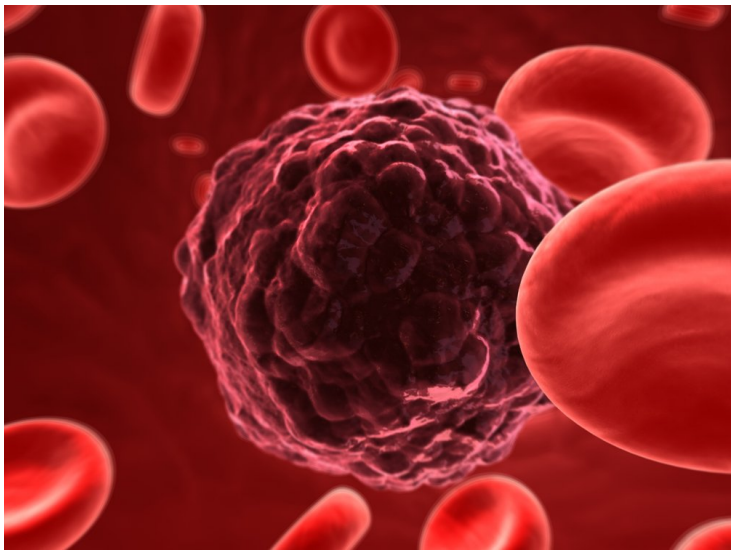

Singapore: Genentech, a member of the Roche Group, has achieved primary endpoint of a significant improvement in HER2-positive metastatic breast cancer (mBC) during phase III EMILIA study of trastuzumab emtansine (T-DM1). The study showed that the risk of disease worsening or death was reduced by 35 percent for people who received trastuzumab emtansine compared to those who received lapatinib plus Xeloda (capecitabine) chemotherapy.

The EMILIA study is the first randomized phase III trial of trastuzumab emtansine in people with HER2-positive mBC who had previously received Herceptin (trastuzumab) and a taxane chemotherapy.

There was also a trend among people who received trastuzumab emtansine to live longer (overall survival) than those who received lapatinib plus Xeloda, but these data are currently not mature. The safety profile of trastuzumab emtansine was consistent with that seen in previous studies, with fewer people who received trastuzumab emtansine experiencing Grade 3 or higher (severe) adverse events than those who received lapatinib plus Xeloda (40.8 percent compared to 57.0 percent).

"The encouraging efficacy, safety profile and quality of life results from the EMILIA study support our belief that trastuzumab emtansine may have an important role for patients with HER2-positive metastatic breast cancer," said Dr Hal Barron, chief medical officer and head, Global Product Development at Genentech. "We are working with global regulatory authorities to submit these data as quickly as possible and hope that trastuzumab emtansine will soon be available to patients with this aggressive type of breast cancer."

Based on the EMILIA findings, Genentech and Roche plan to submit applications for trastuzumab emtansine in HER2-positive mBC this year to the US Food and Drug Administration (FDA) and European Medicines Agency.

Trastuzumab emtansine is an investigational medicine known as an antibody-drug conjugate (ADC). It is comprised of the antibody trastuzumab and the chemotherapy DM1 attached together using a stable linker. Trastuzumab emtansine is designed to target and inhibit HER2 signaling and deliver the chemotherapy directly inside HER2-positive cancer cells.