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Mylan and Biocon has announced the presentation of data from the HERITAGE study at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, June 3-7. The study confirmed the efficacy, safety and immunogenicity of MYL-1401O, the proposed biosimilar trastuzumab co-developed by Biocon and Mylan, in comparison to branded trastuzumab.

"As one of the first companies in the industry to successfully complete a confirmatory efficacy and safety study comparing a proposed biosimilar to a branded cancer drug, this is a significant milestone for Mylan's biosimilar program," Mylan President Mr Rajiv Malik said. "There is an urgent, unmet need for more affordable versions of biologic products and through our collaboration with Biocon we are well-positioned to be at the forefront to help deliver these complex products to patients around the world. We're pleased that ASCO has recognized the importance of biosimilars in advancing cancer care and the significant role they will play in providing patients greater access to affordable treatment."

Dr Kiran Mazumdar Shaw, Chairperson and Managing Director, Biocon, added, "The positive outcomes of the global Phase 3 clinical study with our proposed biosimilar trastuzumab for HER2-positive breast cancer patients are a significant milestone in our joint biosimilars development program with Mylan. The trial will enable regulatory filings of our product in the developed markets. Biocon remains committed to develop affordable biologics and these study results will help us in enhancing access for cancer patients, caregivers and healthcare systems across the globe."

Worldwide, nearly 2 million women are diagnosed with breast cancer each year, making it the second most common cancer in the world. HER2-positive metastatic breast cancer is an aggressive form of breast cancer that tests positive for the human epidermal growth factor receptor 2 (HER2), which promotes cancer cell growth. Approximately 20% to 30% of primary breast cancers are HER2-positive.

Trastuzumab is indicated for the treatment of HER2-positive metastatic breast cancer patients. It is also indicated for adjuvant

treatment of HER2 overexpressing breast cancer and metastatic gastric cancer. It is a targeted therapy that interferes with the HER2 protein and impedes cancer cell growth.

"The HERITAGE study successfully met the predefined endpoints of response equivalency. We are proud of this international collaboration which puts us one step closer to approval of this proposed biosimilar. The response rates at 24 weeks were 69.6% with MYL-1401O combined with taxane chemotherapy versus 64% with branded trastuzumab combined with the same chemotherapy agent. The ratio of overall response and difference in overall response fell within a narrow, pre-defined equivalence margin suggesting equal efficacy of both products. Safety was comparable between treatment groups. The rates of serious adverse events were 38% with MYL-1401O and 36% with branded trastuzumab, and there was no difference in cardiac safety," commented lead study author Dr. Hope S. Rugo, professor of Medicine at the University of California, San Francisco.