



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.