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Mylan N.V. and Biocon Ltd. announced submission of Mylan's biologics license application for MYL-1401O, a proposed biosimilar trastuzumab, to the U.S. Food and Drug Administration (FDA) through the 351(K) pathway. This product is a proposed biosimilar to branded trastuzumab, which is indicated to treat certain HER2-positive breast and gastric cancers. Mylan and Biocon believe that this has the potential to be the first submission of a proposed biosimilar trastuzumab in the U.S.

The submitted BLA includes a comprehensive package of analytical similarity, nonclinical and clinical data. The clinical data consists of two pharmacokinetic studies and the HERITAGE confirmatory efficacy and safety trial. The results of the HERITAGE trial were presented at this year's American Society of Clinical Oncology (ASCO) Annual Meeting and the European Society for Medical Oncology (ESMO) Congress.

Mylan President Rajiv Malik commented: "The FDA submission for biosimilar trastuzumab marks Mylan's first FDA biosimilar submission from our broad portfolio of biosimilar products in development and our product has the opportunity to be the first biosimilar trastuzumab approved in the U.S. This submission also is another demonstration of the strength of the Mylan/Biocon partnership and our shared commitment to increasing access to these critical medicines worldwide. Our trastuzumab biosimilar is already being sold in 11 developing markets, including India, and we look forward to bringing the product to market in the U.S. and Europe upon approval."

Dr Arun Chandavarkar, CEO & Joint MD, Biocon, commented: "The submission of our proposed biosimilar trastuzumab with the U.S. FDA is an important milestone of Biocon and Mylan's joint global biosimilars program and demonstrates our commitment to provide access to high-quality and affordable biologics to patients across the globe. Cancer patients in India and emerging markets have benefited with our trastuzumab and this advancement in the U.S. will enable us to enhance access to this affordable therapy to larger patient pools."