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ASIA EDITION

# US FDA approves Samsung Bioepis' first oncology drug

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**ONTRUZANT was also approved by the European Commission (EC) in November 2017, and has since beenlaunched in a growing number of European countries.**


Samsung Bioepis has announced that the U.S. Food and Drug Administration has approved ONTRUZANT, a biosimilar referencing HERCEPTIN (trastuzumab), across all eligible indications, namely adjuvant treatment of HER2-overexpressing breast cancer, metastatic breast cancer and metastatic gastric cancer or gastroesophageal junction adenocarcinoma in patients who have not received prior treatment for metastatic disease.

ONTRUZANT is Samsung Bioepis' first oncology biosimilar to receive FDA approval, and will be marketed and distributed in the United States (US) by Merck, which is known as MSD outside of the US and Canada.

"For many cancer patients in the US, battling cancer has not only been a health issue, but a considerable financial burden brought on by cancer treatment. Biosimilars are intended to be lower cost, high-quality treatment options that have the potential to alleviate such burden. We sincerely hope our trastuzumab biosimilar will do exactly that," said Sang-Jin Pak, Senior Vice President and Head of Commercial Division, Samsung Bioepis. "At Samsung Bioepis, we will continue to demonstrate our enduring commitment to biosimilars by further strengthening our pipeline and widening the availability of approved treatments for cancer patients across the US."

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Established in 2012, Samsung Bioepis is a biopharmaceutical company committed to realizing healthcare that is accessible to everyone. Through innovations in product development and a firm commitment to quality, Samsung Bioepis aims to become the world's leading biopharmaceutical company. Samsung Bioepis continues to advance a broad pipeline of biosimilar candidates that cover a spectrum of therapeutic areas, including immunology, oncology, ophthalmology and hematology. Samsung Bioepis is a joint venture between Samsung BioLogics and Biogen.