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Amgen and Allergan's KANJINTI gets FDA approval

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Approval based on totality of evidence demonstrating KANJINTI is Biosimilar to Herceptin

Amgen and Allergan plc have announced that the U.S. Food and Drug Administration (FDA) has approved KANJINTI™ (trastuzumab-anns) for all approved indications of the reference product, Herceptin® (trastuzumab): for the treatment of HER2-overexpressing adjuvant and metastatic breast cancer and HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

KANJINTI was proven to be highly similar to, and to have no clinically meaningful differences from, Herceptin based on a comprehensive totality of evidence which included extensive comparative analytical, pharmacokinetic and clinical data. At the time of approval, KANJINTI is the only trastuzumab biosimilar to incorporate the evaluation of a single transition in the clinical study, demonstrating similar safety and immunogenicity in patients who were previously on Herceptin.

"KANJINTI is the second of four biosimilars from Amgen and Allergan's collaboration to be approved by the FDA," said David Nicholson, chief research and development officer at Allergan. "We are proud of the progress being made as we continuously strive to develop and deliver high-quality cancer therapies in collaboration with Amgen."