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Celltrion, Teva announce FDA approval of HERZUMA

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HERZUMA meets the FDA's rigorous standards as a biosimilar to the reference product for the approved indications based on a totality of evidence.



Celltrion, Inc. and Teva Pharmaceutical Industries Ltd. have announced that the U.S. Food and Drug Administration (FDA) has approved HERZUMA [®] (trastuzumab-pkrb), a HER2/neu receptor antagonist biosimilar to HERCEPTIN [®1] (trastuzumab) for the following indications:

- Adjuvant Breast Cancer of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer
  - as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
  - as part of a treatment regimen with docetaxel and carboplatin
- Metastatic Breast Cancer
  - in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer
  - as a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.
- In these indications, patients should be selected for therapy based on an FDA-approved companion diagnostic for a trastuzumab product

“Biosimilars are of growing importance to the oncology community and the approval of HERZUMA may provide more patients access to this important therapy,” stated Woosung Kee, Chief Executive Officer of Celltrion. “This is our second oncology biosimilar approval in the United States in the past month, which reinforces the goal for all of our approved products -- providing broader treatment options for patients and the providers who treat them.”

HERZUMA meets the FDA’s rigorous standards as a biosimilar to the reference product for the approved indications based on a totality of evidence. The FDA approval is based on a review of a comprehensive data package inclusive of foundational analytical similarity data, nonclinical data, clinical pharmacology, immunogenicity, clinical efficacy and safety data. The results

of the clinical development program for HERZUMA demonstrated that there were no clinically meaningful differences in purity, potency and safety between HERZUMA and HERCEPTIN for the treatment of HER2-overexpressing breast cancer for the approved indications.

“We are excited about building Teva’s presence in biosimilars,” said Brendan O’Grady, Executive Vice President and Head of North America Commercial at Teva. “The addition of HERZUMA to our biosimilars portfolio will allow us to leverage our strengths from Oncology and Generics.”

Trastuzumab products have a Boxed Warning which states that treatment with trastuzumab may be associated with cardiomyopathy, infusion reactions, pulmonary toxicity and embryo-fetal toxicity. Please see the full Boxed Warning and additional Important Safety Information in this release and accompanying Prescribing Information.

Celltrion and Teva Pharmaceutical Industries Ltd. entered into an exclusive partnership in October 2016 to commercialize HERZUMA in the U.S. and Canada.