FDA Approves Ogivri as a Biosimilar to Herceptin

Ogivri approved for the treatment of patients with HER2-positive breast or metastatic stomach cancer.

December 11, 2017 By Food and Drug Administration (FDA)

On December 1, 2017, the Food and Drug Administration approved Ogivri (trastuzumab-dkst, Mylan) as a biosimilar to Herceptin (trastuzumab, Genentech, Inc.) for the treatment of patients with HER2-overexpressing breast or metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma).

Health care professionals should review the prescribing information in the labeling for detailed information about the approved uses:

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761074s000lbl.pdf.

Approval was based on comparisons of extensive structural and functional product characterization, animal data, human pharmacokinetic and pharmacodynamic data, and clinical studies including clinical immunogenicity between Ogivri and U.S.-licensed Herceptin. These data demonstrate that Ogivri is highly similar to U.S.-licensed Herceptin and that there are no clinically meaningful differences between the products. Ogivri has been approved as a biosimilar, not as an interchangeable product.

Common expected side effects of Ogivri for the treatment of HER2+ breast cancer include headache, diarrhea, nausea, chills, fever, infection, congestive heart failure, insomnia, cough, and rash. Common expected side effects of Ogivri for the treatment of HER2+ metastatic stomach cancer include neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia. Serious expected side effects of Ogivri include worsening of chemotherapy-induced neutropenia.

Like Herceptin, the labeling for Ogivri contains a Boxed Warning to alert health care professionals and patients about increased risks of cardiomyopathy, infusion reactions, pulmonary toxicity, and embryo-fetal toxicity.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the

postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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