

Ogivri™ (trastuzumab-dkst) – New biosimilar approval

- On December 1, 2017, the [FDA announced](#) the approval of [Ogivri \(trastuzumab-dkst\)](#), [Mylan and Biocon's](#) biosimilar to Genentech's [Herceptin® \(trastuzumab\)](#).
 - Ogivri is the first FDA-approved biosimilar to Herceptin.
- Ogivri shares the same indications as Herceptin:
 - **Adjuvant breast cancer:** adjuvant treatment 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](#); or as a single agent following multi-modality anthracycline based therapy.
 - **Metastatic breast cancer:** in combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer; or as a single agent for treatment of HER2 overexpressing breast cancer in patients who have received ≥ 1 chemotherapy regimens for metastatic disease.
 - **Metastatic gastric cancer:** in combination with [cisplatin](#) and [capecitabine](#) or [5-fluorouracil](#), for the treatment of patients with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.
 - Patients should be selected for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.
- A biosimilar product is a biological agent that is considered highly similar to an already-approved biological drug, known as the reference product. Biological products are generally derived from a living organism and can come from many sources, including humans, animals, microorganisms or yeast.
 - A biosimilar product must show no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
 - In addition, a biosimilar product may only be approved for the indication(s) and condition(s) that have been FDA approved for the reference product, and must have the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product.
- Ogivri has been approved as a biosimilar, **not** as an interchangeable product.
- The approval of Ogivri was based on review of evidence that included extensive structural and functional characterization, animal study data, human pharmacokinetic and pharmacodynamic data, clinical immunogenicity data and other clinical safety and effectiveness data that demonstrates Ogivri is biosimilar to Herceptin.
- Like Herceptin, Ogivri carries a boxed warning regarding the risk of cardiomyopathy, infusion reactions, embryo-fetal toxicity, and pulmonary toxicity.
- Other warnings and precautions include exacerbation of chemotherapy-induced neutropenia.
- The most common adverse reactions vary by indication.

- In adjuvant breast cancer, the most common adverse reactions ($\geq 5\%$) with trastuzumab use were headache, diarrhea, nausea, and chills.
 - In metastatic breast cancer, the most common adverse reactions ($\geq 10\%$) with trastuzumab use were fever, chills, headache, infection, congestive heart failure, insomnia, cough, and rash.
 - In metastatic gastric cancer, the most common adverse reactions ($\geq 10\%$) with trastuzumab use were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia.
- The recommended dosage of Ogivri varies by indication as follows:

Indication	Recommended Dosage
Adjuvant breast cancer (during and following paclitaxel, docetaxel, or docetaxel/carboplatin)	<ul style="list-style-type: none"> • Initial dose of 4 mg/kg as an intravenous (IV) infusion, then 2 mg/kg IV weekly during chemotherapy for the first 12 weeks (paclitaxel or docetaxel) or 18 weeks (docetaxel/carboplatin). • One week following the last weekly dose of Ogivri, administer Ogivri 6 mg/kg IV every three weeks.
Adjuvant breast cancer (as a single agent within 3 weeks following completion of multi-modality, anthracycline based chemotherapy regimens)	<ul style="list-style-type: none"> • Initial dose of 8 mg/kg by IV, then subsequent doses at 6 mg/kg IV every three weeks. • Extending adjuvant treatment beyond one year is not recommended.
Metastatic breast cancer	Alone or in combination with paclitaxel, at an initial dose of 4 mg/kg IV followed by subsequent once weekly doses of 2 mg/kg IV until disease progression.
Metastatic gastric cancer	Initial dose of 8 mg/kg IV followed by subsequent doses of 6 mg/kg IV every three weeks until disease progression.

- Do not substitute Ogivri with [Kadcyla[®] \(ado-trastuzumab emtansine\)](#).
 - For additional dosing information, refer to the Ogivri drug label.
- According to IQVIA, Herceptin had U.S. sales of more than \$2 billion for the 12 months ending on September 30, 2017.
 - Mylan's launch plans are pending due to ongoing litigation. Ogivri will be available as a 420 mg lyophilized powder in a multi-dose vial for reconstitution.



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