

Wednesday, July 11<sup>th</sup>, 2019

**Request for inclusion on guidelines**

Submitted by:

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NCCN Guidelines Panel: Breast cancer

On behalf of Mylan N.V., we respectfully request the Breast Cancer NCCN panel to review the enclosed data for inclusion of the biosimilar trastuzumab Ogivri™ (trastuzumab-dkst) with approved indications for the treatment of HER2 (+) early and metastatic breast cancer, HER2 (+) metastatic gastric cancer, and HER2 (+) metastatic gastroesophageal junction adenocarcinoma.

Specific Changes: Describe trastuzumab as “trastuzumab, trastuzumab-dkst”.

FDA Clearance: Trastuzumab-dkst was approved as biosimilar for trastuzumab by FDA on December 1<sup>st</sup>, 2017 with indications in: The treatment of HER2-overexpressing breast cancer & The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

Rationale: As part of the global efforts to curb out-of-reach prices on life-saving drugs and increase their access, FDA is supporting the biosimilars development; trastuzumab-dkst (Ogivri™) it's the first trastuzumab biosimilar approved by FDA. Beyond that, it's the only biosimilar with 3-years of overall survival in a phase III demonstrating its similitude in efficacy and safety to the originator. These claims are being supported by the attached publications and documents. We acknowledge that some authors are members of your review panel of experts.

1. Rugo HS, et al. Effect of a Proposed Trastuzumab Biosimilar Compared With Trastuzumab on Overall Response Rate in Patients With ERBB2 (HER2)–Positive Metastatic Breast Cancer. JAMA. 2017;317(1):37-47
2. Rugo HS, et al. Effect of a Proposed Trastuzumab Biosimilar Compared With Trastuzumab on Overall Response Rate in Patients With ERBB2 (HER2)–Positive Metastatic Breast Cancer. Supplementary online content: Tables, Protocol and Statistical Analysis Plan
3. Waller CF, et al. Biosimilar trastuzumab-dkst monotherapy versus trastuzumab monotherapy after combination therapy: Final overall survival (OS) from the phase III HERITAGE Trial. J Clin Oncol 37, 2019 (suppl; abstr 1021)
4. Waller CF, et al. Biosimilar trastuzumab-dkst monotherapy versus trastuzumab monotherapy after combination therapy: Final overall survival (OS) from the phase III HERITAGE Trial. Poster presented at ASCO 2019
5. FDA Approval.  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2017/761074Orig1s000TOC.cfm](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761074Orig1s000TOC.cfm) (Accessed June 24th, 2019)
6. FDA PI.  
<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=761074> (Accessed June 24th, 2019)

With kind regards,



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Head, Global Medical Affairs



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