

Submitted by:

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NCCN Guidelines Panel: Breast Cancer

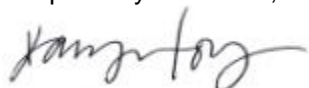
On behalf of Genentech, I am providing published data to the NCCN Breast Cancer Guideline Panel on Perjeta® (Pertuzumab) for the neoadjuvant treatment of early stage HER2-positive breast cancer.

Specific Changes: There are no changes being requested. We are providing published data on the use of Perjeta for the neoadjuvant treatment of HER2-positive early stage breast cancer for your review.

FDA Clearance: Perjeta is not FDA-approved for the neoadjuvant treatment of patients with HER2-positive breast cancer.¹ The FDA has granted a priority review of the supplemental Biologics License Application (sBLA) for Perjeta in this setting and will make a decision on approval by October 31, 2013.² Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.¹

Rationale: Genentech, Inc. recently announced the acceptance of its sBLA for the use of a Perjeta regimen before surgery in patients with HER2-positive early stage breast cancer by the FDA. The sBLA is based primarily on results from NEOSPHERE and TRYPHAENA, two Phase II studies of Perjeta in HER2-positive early breast cancer. We are providing copyright-paid reprints of these two published studies for your review.

Respectfully submitted,



References

1. Perjeta (Pertuzumab) Prescribing Information
2. FDA grants Genentech's Perjeta regimen priority review for use before surgery in HER2-positive early stage breast cancer [press release]. Available at: <http://www.gene.com/media/press-releases/14467/2013-07-01/fda-grants-genentechs-perjeta-regimen-pr>.
3. Schneeweiss A, Chia S, Hickish T, et al. Pertuzumab plus trastuzumab in combination with standard neoadjuvant anthracycline-containing and anthracycline-free chemotherapy regimens in patients with HER2-positive early breast cancer: a randomized Phase II cardiac safety study (TRYPHAENA) [supplementary appendix appears online]. Ann Oncol. E-pub Date: [published online ahead of print] 2013. DOI # 10.1093/annonc/mdt182.
4. Gianni L, Pienkowski T, Im Y-H, et al. Efficacy and safety of neoadjuvant pertuzumab and trastuzumab in women with locally advanced, inflammatory, or early HER2-positive breast cancer (NeoSphere): a randomised multicentre, open-label, Phase 2 trial. Lancet Oncol 2012;13:25-32.