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. 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. Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

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