Genentech
A Member of the Roche Group

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NCCN Guidelines Panel: Breast Cancer

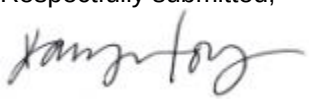
We are aware that the NCCN Guidelines Panel for Breast Cancer will be convening June 24-26, 2012 and acknowledge NCCN's request for scientific data no less than 21 days prior to the scheduled meeting. As such, we would like to make you aware of a pending Biologics License Application for pertuzumab, whose approval is anticipated shortly prior to the Panel meeting.

FDA Clearance: Pertuzumab is not FDA-approved. Our FDA action date is June 8, 2012.[1]

Enclosed for your review is a copyright-paid reprint of the published CLinical Evaluation Of Pertuzumab And TRAstuzumab (CLEOPATRA) trial.[2] This Phase III, randomized, double-blind, placebo-controlled study compared the efficacy and safety of pertuzumab in combination with trastuzumab and docetaxel to trastuzumab plus docetaxel alone as first-line treatment for HER2-positive metastatic breast cancer. This trial forms the basis of our FDA submission.

We will communicate final approval once received by the FDA.

Respectfully submitted,



References

1. FDA Grants Genentech's Pertuzumab Priority Review for Previously Untreated HER2-Positive Metastatic Breast Cancer [press release]. South San Francisco, California; February 7, 2012. Accessed June 1, 2012 from http://www.gene.com/gene/news/press-releases/display.do?method=detail&id=13847.
2. Baselga J, Cortés J, Kim S-B, et al. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. N Engl J Med 2012;366:109-119.