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,

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**References**
