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A Member of the Roche Group

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December 23, 2010

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
United States Food and Drug Administration
c/o Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Subject: **Request for Hearing**
License No. 1048
STN: BL 125085
Avastin® (bevacizumab) for metastatic breast cancer

Re: Docket No. FDA-2010-N-0621

Dear Dr. Woodcock:

In accordance with 21 C.F.R. § 601.43, Genentech hereby requests a hearing on FDA's proposal to withdraw the approval of Avastin® (bevacizumab) for use in combination with paclitaxel to treat patients who have not received chemotherapy for metastatic HER2-negative breast cancer (mBC) (STN: BL125085/91). This request for a hearing timely responds to the Notice of Opportunity for a Hearing that Genentech received from the Center for Drug Evaluation and Research on December 16, 2010. Genentech will make the submission on which it intends to rely at the hearing to support Avastin's mBC indication by January 18, 2011, a date Genentech has confirmed with the FDA's Office of Chief Counsel.

It would be inappropriate to deny a hearing in this matter under 21 C.F.R. § 601.43(c) and 21 C.F.R. part 15. Genentech's January 18, 2011 submission will set forth legal authority, data, information, and analyses supporting its right to a hearing, including by demonstrating that there are genuine and substantial issues of material fact that require a hearing. The January 18, 2011 submission will also include our view as to why a hearing is particularly warranted here given the two years of clinician and patient reliance on this important indication, along with the contrary views that the European Medicines Agency reached on the same data supporting the use of Avastin with paclitaxel in mBC. Finally, the submission will address the broader policy implications of the Agency's decision, which further justify a hearing.

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An extensive data set supports the continued accelerated approval of Avastin in combination with paclitaxel. Avastin has shown significantly improved rates of progression-free survival for first-line treatment of HER2-negative mBC patients in three well-designed clinical trials, with the largest magnitude of effect observed when Avastin is used in combination with paclitaxel. These benefits are underscored by clinical experience: Avastin has become an important option for physicians and patients seeking to control this incurable form of cancer, and its importance continues to be recognized in consensus treatment guidelines. At the same time, Avastin's safety profile is well-characterized, with no new safety signals observed in the recent clinical trials, allowing for an informed choice by patients and physicians.

Based on the data, governing statute and regulations, and the public health, withdrawal of Avastin's indication for the treatment of mBC is not justified. We look forward to the opportunity to present our views more fully on these important issues.

Sincerely,

Michelle H. Rohrer, Ph.D.
Vice President
Regulatory Affairs

cc(s): John Jenkins, M.D., Director, Office of New Drugs, Center for Drug Evaluation and Research

Richard Pazdur, M.D., Director, Office of Oncology Drug Products, Center for Drug Evaluation and Research

Patricia Keegan, M.D., Director, Division of Biological Oncology Products, Center for Drug Evaluation and Research