DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125019/135

MAR 25 2008

Biogen Idec, Inc.
Attention: Nancy Boman, M.D., Ph.D.
Vice President Regulatory Affairs,
Cell Therapeutics, Inc.
501 Elliot Avenue W
Seattle, WA 98119

Dear Dr. Boman:

Your request to supplement the biologics license application for Zevalin (Ibritumomab tiuxetan) to remove the transformed B-cell non-Hodgkin's lymphoma (NHL) indication from the package insert and to convert the package insert label to the format specified in 21 CFR 201.56 and 201.57 has been approved.

You are hereby released from the requirement under 21 CFR 601.40-46 to conduct postmarketing commitment (PMC) # 2 identified in the February 19, 2002, approval letter for your biologics application, STN 125019/0, to verify the clinical benefit of Zevalin for the transformed B-cell NHL indication:

> PMC #2: To verify the clinical benefit and further assess the safety and efficacy of the Zevalin therapeutic regimen in patients with transformed CD20+ B-cell NHL. For this study, the primary efficacy variables will be overall response rate and duration of response. Other measures of clinical benefit will include event-free survival, time to progression and quality of life and disease-related symptoms, including B symptoms.

The following postmarketing commitment to verify clinical benefit from the February 19, 2002, approval letter for STN 125019/0 remains open:

> PMC #1: To verify the clinical benefit and further assess the safety and efficacy of Zevalin radioimmunotherapy in patients with chemotherapy relapsed or refractory follicular NHL. This will be assessed in a randomized, multicenter study to establish the net clinical benefit of the Zevalin therapeutic regimen used in combination with Rituxan as compared to Rituxan therapy alone. For this study, the primary efficacy variable will be event-free survival defined as absence of disease progression, initiation of additional lymphoma therapy, or death from any cause. Uniform criteria will be used to define when additional anti-lymphoma treatment is initiated including the presence of disease-related symptoms, threatened end-organ function, cytopenias secondary to NHL, massive bulk disease, or steady disease progression over at least 6 months without meeting the definition of progressive disease. The final protocol will be submitted to FDA by May 30, 2002. Completion of subject accrual and the study are anticipated by

November 30, 2004 and May 30, 2006, respectively. A final clinical study report will be submitted by August 30, 2006.

You are still obligated to meet the requirements of PMC #1 or you must submit an acceptable replacement that is agreed to by FDA.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 125019/135." In addition, within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

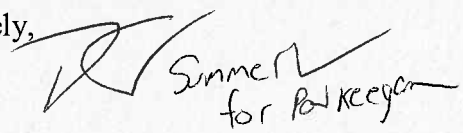
We remind you that as required by 21 CFR 601.45, you must submit all promotional materials at lease 30 days before the intended time of initial distribution of labeling or initial publication of the advertisement with a cover letter requesting advisory comment. Send two copies of the promotional materials to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communication, 5901-B Ammendale Road, Beltsville, MD 20705-1266. Please submit final promotional materials with FDA Form 2253 to the above address at the time of initial dissemination of the labeling or at the time of initial publication of the advertisement.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

Please refer to http://www.fda.gov/cder/biologics/default.htm for information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

Sincerely,



Patricia Keegan, M.D.
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