



DEPARTMENT OF HEALTH AND HUMAN SERVICES

TELECONFERENCE MEMORANDUM

Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

Date\Time: February 28, 2007

CBER Representatives: Peter Bross, Boguang Zhen, Ke Liu, Lori Tull

Sponsor's Representative: Elizabeth Smith, Mark Frohlich, Lianng Yuh

STN : 125197/0

Subject: Clinical and Statistical Questions

Discussion:

CBER asked Dendreon to clarify the post progression chemotherapy use as related to survival by submitting curves for time to chemotherapy and time to Docataxel from time of progression. Dendreon stated that this was located in the BLA in the summary of clinical efficacy, survival robustness analysis.

CBER asked if Dendreon had looked at time from initial randomization to chemotherapy or any type of post progression therapy. Dendreon responded that they did the analyses, and it looked like there was a positive treatment effect. Dendreon agreed to submit these analyses to the BLA.

CBER asked if Dendreon planned to present at the advisory committee any information about strokes. Dendreon responded that they would, but they don't think there is an association. CBER stated that they considered it to be a safety signal. Dendreon said that they would make a pharmacovigilance plan for CVA events if needed.

CBER noted that they could not find the Phase 1 and 2 datasets in the stats folder. Dendreon responded that they did not submit that information to the BLA. CBER asked if it would be in the safety update. Dendreon responded that the safety update would contain the unblinded P11 data, blinded 9902B data, and safety data from study 9906 (Japan). Dendreon stated that they looked at events in the controlled studies and all trials.

CBER asked Dendreon to prepare a summary for the ten events or to tell where it was located in the BLA. CBER also requested for CD54 upregulation and survival for Dendreon to prepare an analysis for baseline prognostic factors for high and low CD54.

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• *Toni A Tull*

APPROVED

By tull at 2:41 pm, Apr 20, 2007