



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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TELECONFERENCE MEMORANDUM

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

**Date\Time:** February 14, 2007 \ 1-2 pm

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

**Sponsor's Representative:** Mark Frohlich (Clinical Affairs), Helen Kim (Regulatory Affairs)  
David Marcus (Biometrics), Amy Myers (Clinical Affairs), Dave Urdal (Chief Scientific  
Officer), Liangng Yuh (Biometrics)

**STN :** 125197/0

**Subject:** Revised Time to Progression (TTP) data analysis

**Discussion:**

CBER began the discussion by stating that the reason for the call was to discuss Dendreon's plans concerning the results of their revised TTP data analysis that brought the p-value to 0.048.

Dendreon responded that they planned to use that p-value (0.048) as the p-value for the study.

CBER asked if Dendreon would now be changing their endpoint to TTP instead of survival.

Dendreon responded that their endpoint for the BLA submission would remain as survival.

CBER then advised Dendreon that if they would be presenting the p-value of 0.085 to the advisory committee. If Dendreon wanted CBER to consider the p-value of 0.048 as the p-value for the study, the advisory committee would have to be cancelled, so that CBER would have time to reevaluate the data. CBER suggested that Dendreon submit the new p-value as an exploratory finding only.

Dendreon responded that they did not want to cancel the advisory committee. They agreed not to make any claim that the p-value of the study had changed to 0.048, but would only say that they obtained this new p-value as a result of reanalyzing the data.

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