



DEPARTMENT OF HEALTH AND HUMAN SERVICES

TELECONFERENCE MEMORANDUM

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

March 6, 2007
2 pm EST

Dendreon participants
Nicole Provost
Elizabeth Smith

FDA participants
Keith Wonnacott
Kimberly Benton
Thomas Finn
Rafat Husain
Malcolm Moos

Minutes

We clarified that we wanted to get an overview of the data that Dendreon has collected on immune responses during their clinical trials. We said we were most interested in how those immune responses might correlate with product characteristics, such as CD54 upregulation.

Nicole Provost then walked us through a summary of the data that was contained in the BLA and in the Dendreon briefing document for the advisory committee. Only 49 patients in D9901 were measured for immune response (31 in the treatment arm and 18 in the placebo arm) and no patients were measured for immune response in D9902a. They are attempting to collect this data in a more systematic fashion in the ongoing D9902b study. The data collected so far included:

- T cell stimulation (measured as a stimulation index of culture with and without antigen)
- Antibody responses
- NK cell responses

We asked several questions including:

CBER: Was there an analysis to see if immune response correlated with CD54 upregulation?

Dendreon: No

CBER: Why don't you detect a response against PAP alone?

Dendreon: We don't know why T cells respond to PA2024 and not seminal PAP.

We concluded that these data do not provide much information on product quality. However, we don't know how we would respond if the data had shown a correlation between immune response and a product characteristic (positive or negative). We encouraged them to continue collecting immune response data.