



DEPARTMENT OF HEALTH AND HUMAN SERVICES

TELECONFERENCE MEMORANDUM

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

Date\Time: February 5, 2007 \ 1-2 pm

CBER Representatives: Ke Liu, Boguang Zhen, Peter Bross

Sponsor's Representative: Elizabeth Smith

STN : 125197/0

Subject: Dendreon Imaging Data Request, clarify data/statistical issues

Questions to Dendreon:

In the protocol, section 2.1, the primary endpoint is identified as "time to objective disease progression:"

"Objective disease progression" is defined as:

- >Progression of measurable disease;*
- >Progression of evaluable disease (e.g., bone scan);*
- >Spinal cord compression or a pathologic fracture at the site(s) of known disease;*
- >Development of a requirement for radiation therapy;*
- >Development of other clinically significant disease-specific events including disease-related pain or other disease-related symptoms.*

The 9901 study report, section 11.4.1 lists the primary endpoint as "time to disease progression," as defined by

- >Progressive disease on serial radiographic imaging tests,*
- >New cancer-related pain associated with a radiographic anatomical correlation, or*
- >Other clinical events consistent with progression such as spinal cord compression, nerve root compression or pathologic fracture.*

And figure 4 shows the KM curves and the log rank p of 0.052. Were there any differences between the endpoint that was analyzed in this "time to disease progression," analysis and the protocol-defined primary endpoint of "time to objective disease progression?"

The confusion arises because Section 11.4.2 lists a separate analysis for "time to objective disease progression confirmed by imaging studies," with an associated log rank p=0.183. Could you clarify if this use of "time to objective disease progression" is in fact a measurement of the "time to radiologic progression" and just a subcomponent of the protocol defined "time to objective disease progression" and analyzed as "time to disease progression," in the study report?

Was this use of "objective disease progression" defined in section 8.1 "criteria for evaluation" in the protocol which defined radiological progression?

Dendreon Response:

The sponsor confirmed that the primary endpoint described as “time to objective disease progression” in the protocol is the same as “time to disease progression” in the study report. They just used different terminology.

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