

Date: 3-20-07

Time: 3:30 pm EST

Participants:

FDA: Ke Liu, Peter Bross, Zhen, Boguang

Dendreon: Liz Smith, Mark Frohlich, Lianng Yuh, Christopher Logothetis

Telecon:

1. CVA events:

The sponsor would like to present the slide 51 of their presentation slides, proposing to take 100 out from the placebo for CVA analyses. By doing so, CVA events in the placebo group would be higher (4.6%) instead of 2.6%.

Bo: misleading because the patient selection bias, patients selected out may be different from the placebo group.

Ke: Agree with Bo's comments. Mentioned about the salvage treatment did not contribute to the efficacy evaluation separately, what is the reason now to separate them from safety analyses. Also, the salvage products were different from Sipeuleucel T, and thus not reasonable to combine them with APC8015.

Peter said that he agreed that he did not recommend the sponsor to take the 100 subjects out from APC-placebo for CVA analyses, but FDA would have more discussion.

Sponsor still insisted on the taking 100 subjects out because of the subjects who received the frozen product should be accounted as receiving the active treatment.

Ke proposed that the sponsor make a footnote under the CVA events table to describe that there were no CVA events in 100 salvage patient without change any numbers.

Consensus was not reached. FDA did not agree with the sponsor's proposal. FDA did not recommend that the sponsor present the data to AC panel because the data are misleading as presented in slide 51. However, FDA made suggestions on how to incorporate the CVA events in salvage patients for the sponsor's AC presentation.

2. Safety database:

The sponsor stated that the safety update was already submitted yesterday to include information from D9902B (blinded), P-11. No update for D9901 and D9902A which were already submitted in original submission and amendments.

3. FDA presentation slides:

Still in draft form. Peter would like the sponsor to see the FDA's draft slide on Survival to see whether the sponsor has any comment.

Action items:

1. Liz Smith to send an email to point out the location of salvage patients efficacy data that were contained in the BLA (original submission and amendments)
2. Ke emails Liz Smith one or two slides that describes Survival in the study design
3. FDA internal discussion on the final recommendation to the sponsor on how to include the CVA events in the salvage patients in AC presentation.