

(System Info - 126759 Smith Elizabeth 04/22/2010 18:56:44 TULL)

From: Smith, Liz [lsmith@Dendreon.com]
Sent: Tuesday, February 06, 2007 9:07 AM
To: Bross, Peter F (CBER); Liu, Ke; Zhen, Boguang (CBER)
Cc: Tull Lori

Attachments: t_DP_CSRt33_u9137-014_t33u.rtf; 9125-072 Query.pdf; FDA Response_DP Changes_Final-hk.xls; KM_DP01_20070205 (2).doc; Subject 9125-017 Query.pdf

Dear Peter, Ke, and Bo:

Thank you for the call yesterday. As discussed, attached is a spreadsheet that identifies each time the p value changed for the primary endpoint (TTP) for 9901 with supporting information. Specifically, for each date change, we have included:

- Subject #
- Treatment assignment
- Randomization date
- Original description from the BLA
- Initial and new progression dates
- Rationale for the date change
- References to the supporting documentation

In most cases, supporting documentation is already contained in CRFs or queries in the BLA for each subject. However, for Subjects 9125-017 and 9125-072, supporting queries are attached. We are awaiting the supporting documentation from --(b)(4)-- for Subject 9137-014 and will send that along when I get it.

Due to the errors identified (with your help!) in Appendix 16.1.9.10, please consider the attached spreadsheet as the definitive information for the progression date changes. Also, we recalculated the TTP log rank p value and HR after the date change for Subject 9137-014. The new p-value (2 sided, Log Rank) is 0.048 and the HR is 1.455. I have attached an updated SAS output reflecting this change.

We are working on your other requests and will get back to you within the next week.

Thanks so much. Please feel free to e-mail or call me.

Best, Liz

Elizabeth C. Smith
Vice President of Regulatory Affairs
Dendreon Corporation
3005 First Ave
Seattle, WA 98121
t: 206.829.1556/ f: 206.219.1004/ m. 206.719.4366
esmith@dendreon.com

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