



January 7, 2010

Food and Drug Administration
Center for Biologics Evaluation
and Research
1401 Rockville Pike
Rockville MD 20852-1448

Kerry Donahue, Esq.
Bellinger & Donahue
6295 Emerald Parkway
Dublin, OH 43016

Dear Mr. Donahue:

This is in response to your letter dated November 23, 2009, on behalf of CareToLive (CTL), expressing your interest in the status of the biologics license application (BLA) submitted by Dendreon Corporation (Dendreon) for Provenge[®], a cancer vaccine to treat prostate cancer. In your letter, you indicate that you are following up on the response from the Food and Drug Administration (FDA), dated May 21, 2009, to the citizen petition filed by CTL (docket number FDA-2007-P-0168). Specifically, you ask that FDA: 1) abide by its commitment for "expeditious review" of Dendreon's amendment to its existing BLA for Provenge[®], as stated in FDA's response to CTL's petition; and 2) meet with CTL representatives and others, if approval for Provenge[®] by Christmas of 2009 is not possible.

As stated in our May 2009 response to CTL's petition, we share your concern for men suffering from advanced prostate cancer, and we reaffirm our goal of approving new products, such as Provenge[®], as soon as they are shown to be safe and effective. We intend to keep our commitment to expeditiously review Dendreon's recently submitted amendment to its existing BLA¹. Please be assured that we will make a determination of the safety and effectiveness of Provenge[®] based on the scientific data provided.

I appreciate your interest in meeting to discuss the issues raised in your letter. However, FDA cannot discuss matters with respect to a pending BLA without the express authorization of the sponsor. Therefore, at this time, we respectfully decline your request for a meeting.

Sincerely,

A handwritten signature in black ink that reads "Karen Midthun".

Karen Midthun, M.D.

Acting Director

Center for Biologics Evaluation and Research

cc: Division of Dockets Management
(HFA-305)

¹ We note that Dendreon issued a press release on November 20, 2009, announcing that FDA had provided written acknowledgment of Dendreon's amendment to its existing BLA for Provenge[®].