



Official Meeting Summary

Application type and number: STN 125197
Product name: Sipuleucel-T
Firm: Dendreon Corporation
Meeting category: Post-marketing Requirement
Meeting date & time: March 24, 2010, 1:30 pm – 2:30 pm
Meeting format: Teleconference
Meeting Chair/Leader: Craig Zinderman, MD, MPH
Meeting Recorder: Christopher Le, MS, MLS(ASCP)

FDA Attendees:

Rickey Wilson, MD, MS, JD, Division Director, CBER/OBE/DE
Robert Wise, MD, MPH, Deputy Division Director, CBER/OBE/DE
Craig Zinderman, MD, MPH, CBER/OBE/DE/TBSB
Christopher Le, MS, MLS(ASCP), Regulatory Project Manager, OBE/DE

Dendreon Corporation Attendees:

Mark Frohlich, Chief Medical Officer, SVP Clinical Affairs
Majid Tabesh, VP Medical Affairs
Helen Kim, Director, Regulatory
James Whitmore, VP Biostats
Joan Holman, Sr. Director, Drug Safety
Elizabeth Smith, VP of Regulatory Affairs

Background and Objectives:

FDA requested a meeting to discuss the post-marketing requirement (PMR) protocol for Sipuleucel-T, an active cellular immunotherapy product designed to stimulate an immune response against prostate cancer. The proposed indication is treatment of men with metastatic castrate resistant (hormone refractory) prostate cancer.

Discussion:

Dr. Zinderman stated the purpose of the meeting and asked Dendreon representatives to provide a summary and status update on their plans for the registry study which they will be using to fulfill the PMR. Dendreon's registry study will be a multi-center, observational safety and survival follow-up registry. Registry will be strictly observational. Physicians will record all adverse events within 30 days of the last infusion and will record all treatment-related adverse events and cerebrovascular events (CVEs) throughout enrollment. Baseline information

including demographics, disease status, medical history, and prognostic factors will be collected for comparison to other databases. Dendreon will collect results of relevant laboratory value parameters if already available in the clinical record, but will not be requesting any additional laboratory testing. FDA suggested that a fair amount of data should be available in the database, and elements not available in the database might be available with the physicians.

Sample size. FDA concluded that 1,500 to 2,000 subjects is a sufficient sample size to detect an increased relative risk of 2.7 to 3.0 compared to the SEER-Medicare database. Dr. Wilson explained that the usual convention is to ensure adequate sample size to detect a doubling in relative risk. However, taking into account the severity of the underlying disease and the need that the patient population has for this treatment (with no alternative treatment available at such a severe stage of the disease process), FDA has determined the ability to detect a large increase in relative risk of 2.7 to 3.0 is adequate for this study. A minimum of 1,500 overall subjects is required to adequately quantify the adverse events and survival time in the treated population. Dendreon proposed to include at least 200 African-Americans in the registry population to quantify survival time and adverse events for African-American patients in comparison to non-African-American patients. The target number of 200 may need adjustment during patient accrual based on the number of African-Americans agreeing to participate. The timeline for completion of the study is based on the total population of 1500, not on the 200 African-American patients. FDA agrees this is appropriate.

Dendreon will encourage all treating sites to participate as registry sites with the goal of more than half of the sites participating. This allows Dendreon to focus on sites with quality data and capability to do the registry. FDA suggests keeping a record of all patients receiving the product even if not a registry site, so that retrospective comparisons can be done later, if needed. Dendreon responded that they already have access to this information due to the autologous nature of the product.

Action items:

Dendreon to send Dr. Zinderman an email outlining the variable to include in the protocols and a list of prognostic factors for CVEs that will be collected as background data on enrollees.

Dr. Zinderman to check with Lori Tull whether the PMRs should continue to be submitted to the IND

Follow-up teleconference in 2 – 3 weeks

END

Application Number: BLA 125197

Letter Type: Meeting Summary (MS)

cc: Division Files
EDR/Review Committee

History:

File Name: