

Dendreon – sipuleucel-T (Provenge) - BLA STN 125197

For the treatment of men with asymptomatic metastatic androgen independent prostate cancer

First BLA Review Committee Meeting, November 29, 2006

1. Introduction of Committee Members	(Phone)
Product - Keith Wonnacott	827-5151
Malcolm Moos	827-0683
Tom Finn	827-5146
Syed Husain	827-0673
Clinical – Ke Liu	827-5349
Pharm/Tox – Yongjie Zhou	827-5345
DMPQ – Pat Padgett	827-3031
Gang Wang	827-7123
BIMO – Bhanu Kannan	827-6188
Statistics – Bo Zhen	827-6027
Epidemiology – Kathryn O’Connell	827-6059
Labeling – Catherine Miller	827-3028
RPM – Lori Tull	827-5359
Mark Davidson	827-5358

2. Official Milestones and Monthly Goals

First committee meeting	on or prior to 12/4/06 (Sched 11/29/06)
Filing meeting	on or prior to 12/28/06 Sched 12/19/06)
Filing action	on or prior to 1/12/07 (Letter)
Deficiencies identified	on or prior to 1/26/07 (Letter)
First action due	on or prior to 5/15/07
Monthly update meetings	

3. Regulatory history/review of agreements with sponsor

4. Review Expectations

5. Review Updates

6. Advisory committee updates

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