

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

For the treatment of men with asymptomatic metastatic androgen independent prostate cancer  
**BLA Mid Cycle Meeting, February 27, 2007**

**1. Overview (5 min)**

- Updated timeline
- Advisory Committee – CGTAC, March 29, 2007
- Milestones – Action due May 15, 2007

**2. Status of Product Review (20 min)**

- Questions
- Issues for sponsor discussion

**3. Status of Pharm/Tox Review (5 min)**

**4. Status of Clinical/Statistical Review (5 min)**

- Questions
- Issues for sponsor discussion

**5. Status of Facility Reviews and Inspections (15 min)**

**6. Status of BIMO inspections (15 min)**

**7. AC meeting (20 min)**

- Latest agenda

**Additional Discussion Items (10 minutes)**

- **Agenda for Thursday's tcon w/Dendreon**

**Action Items (5 min)**

Finalize questions for AC mtg. – mtg next week

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