

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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