The Provenge® (sipuleucel-T) Experience
– A Regulatory Perspective

2007 iSBTc Annual Meeting ‘Hot Topics’
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David L. Urdal

The following relationships exist related to this presentation:

- I am employed by Dendreon
- I own stock in Dendreon
- I will be discussing development of a Dendreon product candidate
Sipuleucel-T is an autologous investigational active cellular immunotherapy product that activates the immune system against prostate cancer.
Sipuleucel-T: Patient-Specific Product

Day 1
Leukapheresis

Day 2-3
sipuleucel-T is manufactured

Day 3-4
Patient is infused

Apheresis Center

Dendreon

Doctor’s Office

COMPLETE COURSE OF THERAPY:
Weeks 0, 2, 4
The Phase 3 Plan

- Two identical Phase 3 multi-center, double-blind, randomized, placebo controlled trials
  - D9901
  - D9902A
- Target population: asymptomatic, metastatic androgen independent prostate cancer
- Well-defined manufacturing process
- Potency and other release specifications established
Sipuleucel-T Overall 3-Year Survival Intent-to-Treat Study D9901

- p-value = 0.01 (log rank)
- HR = 1.7
- Median Survival Benefit = 4.5 months

**Placebo (n=45)**
- 11% at 3 years

**Sipuleucel-T (n=82)**
- Median Survival: 25.9 mos.
- 34% at 3 years

Clinical Safety Conclusions
Known Adverse Drug Reactions

- Most frequent events associated with product infusion
  - Chills
  - Pyrexia
- Adverse drug reactions
  - Generally mild to moderate in severity
  - Majority resolved within 24 hours
- <3% of patients unable to receive all 3 infusions due to treatment-related adverse events
Sipuleucel-T Proposed Basis for Licensure

- Randomized, double blind, placebo-controlled studies
- Primary Evidence: D9901
  - Survival
    - Statistically robust, internally consistent findings
    - Confirmed in multiple sensitivity analyses
  - Time to disease progression
    - Trend toward a delay
- Supportive evidence
  - Trend in overall survival in D9902A
  - Integrated analyses
  - Survival correlates with product potency
- Demonstrated safety and tolerability
Pre-BLA Meetings (Clinical and CMC)

• The Center for Biologics Evaluation and Research (CBER)
  — Office of Cellular, Tissue and Gene Therapies (OCTGT)

• Key Agreements
  — Survival benefit observed in Study D9901
  — Supported by D9902A and the absence of significant toxicity
  — Will serve as the clinical basis of a BLA for PROVENGE
  — Additional clinical trials not required from a CMC perspective
  — Potency assay and proposed release parameters
Regulatory Timeline

- **Sept 05**: Pre-BLA Meeting
- **May 07**: Complete Response Letter
- **Mar 29, 2007**: CTGTAC Meeting
- **Nov 06**: CMC Section
- **Aug 06**: Non-Clinical and Clinical BLA Sections
- **Mar 07**: Safety Update
- **2007**: Complete Response Letter
Cell, Tissue and Gene Therapy Advisory Committee

- Committee Representation
- Key Questions to the Committee
  - Is sipuleucel-T reasonably safe for the intended patient population?
    17 yes – 0 no
  - Has substantial evidence of efficacy been established?
    13 yes – 4 no
The Preliminary Outcome

- Request for additional clinical and CMC information
The Promise

- D9902B
  - Enrollment complete
  - Positive interim or final survival analysis sufficient for BLA amendment

- Commitment moving forward