



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

2007 iSBTc Annual Meeting 'Hot Topics'
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David L. Urdal Ph.D.
Chief Scientific Officer

Dendreon
Targeting Cancer, Transforming Lives™

Forward Looking Statements

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Presenter Disclosure Information

David L. Urdal

The following relationships exist related to this presentation:

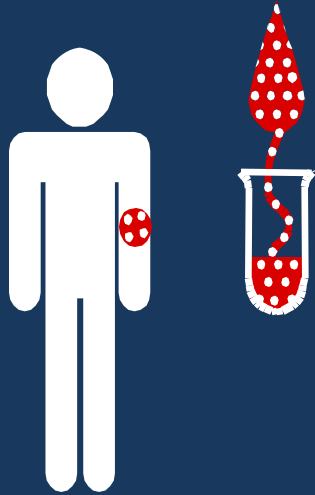
- *I am employed by Dendreon*
- *I own stock in Dendreon*
- *I will be discussing development of a Dendreon product candidate*

Sipuleucel-T

Sipuleucel-T is an autologous investigational active cellular immunotherapy product that activates the immune system against prostate cancer

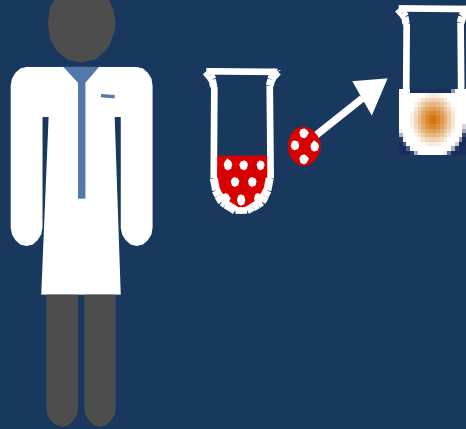
Sipuleucel-T: Patient-Specific Product

Day 1
Leukapheresis



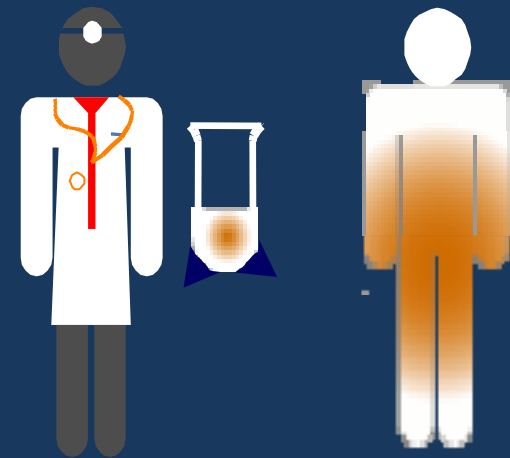
Apheresis Center

Day 2-3
sipuleucel-T is
manufactured



Dendreon

Day 3-4
Patient is infused



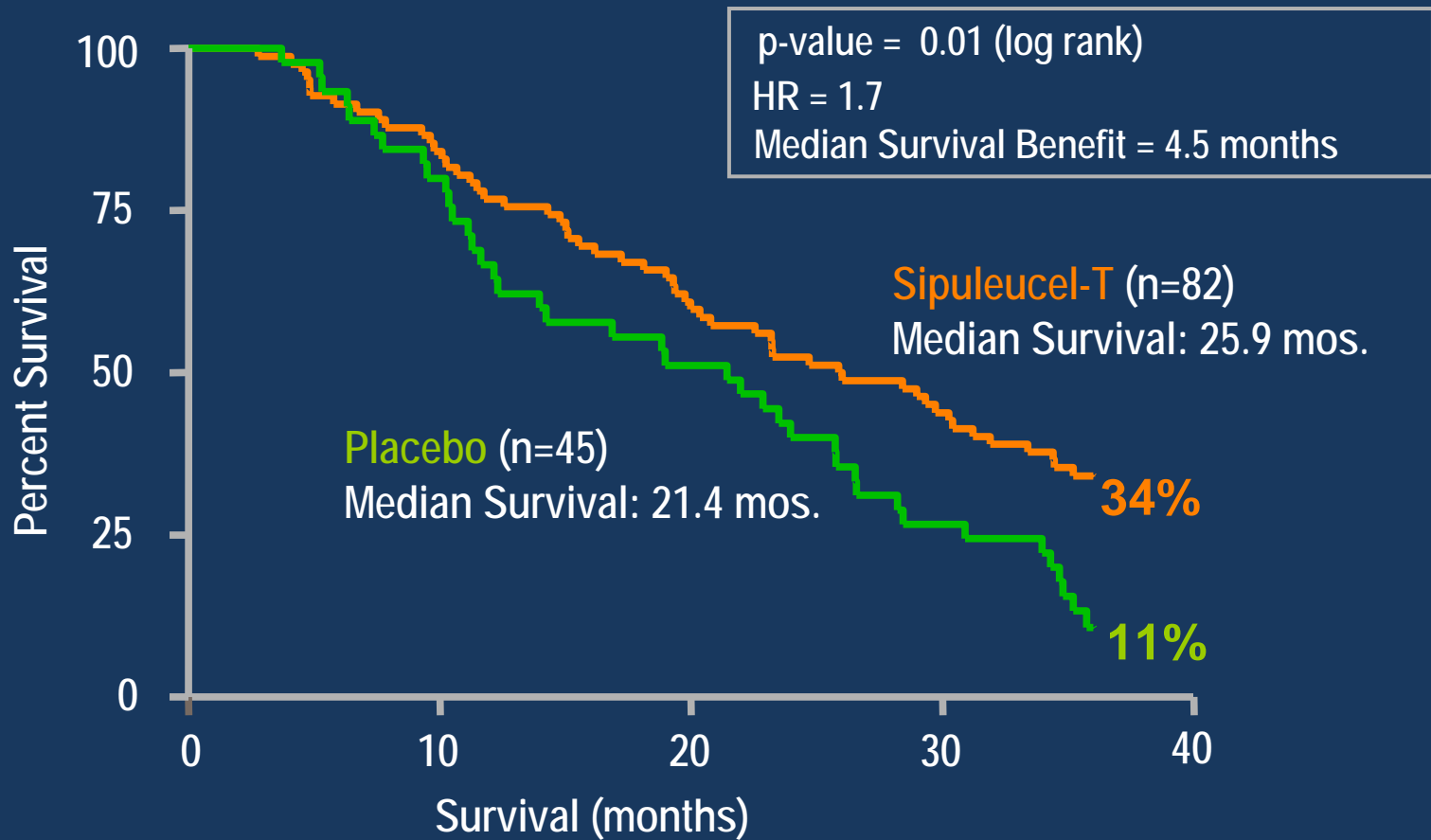
Doctor's Office

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



Small EJ, Schellhammer PF, Higano CS, et. al. Placebo-Controlled Phase III Trial of Immunologic Therapy with Sipuleucel-T (APC8015) in Patients with Metastatic, Asymptomatic Hormone Refractory Prostate Cancer. *J Clin Oncol* 24:3089-3094, 2006

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

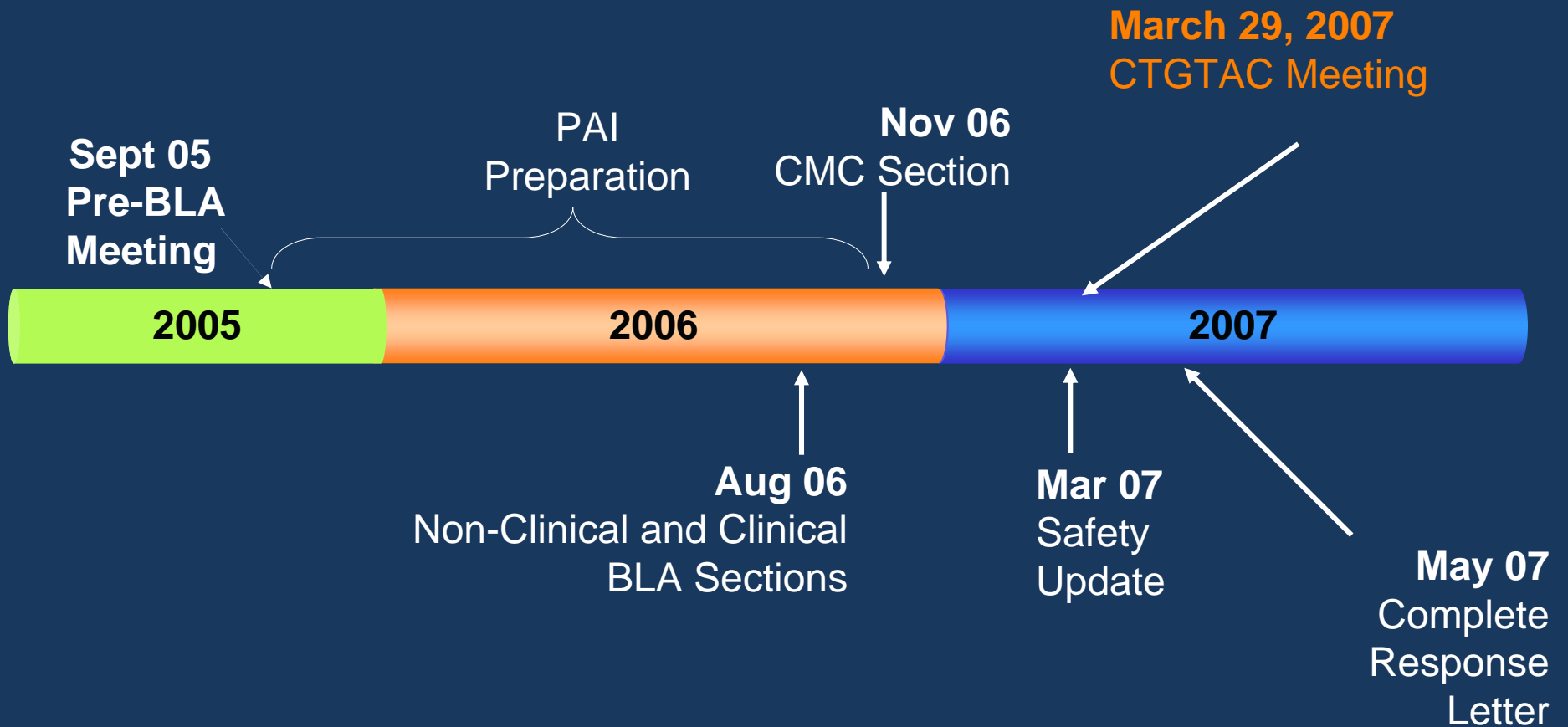
Sipuleucel-T Proposed Basis for Licensure

- 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



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

- Complete Response Letter – May 8, 2007
- 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