



Dendreon

Targeting Cancer, Transforming Lives™

David L. Urdal, Ph.D.
Chief Scientific Officer

The Development of Sipuleucel-T (Provenge®) for Active Cellular
Immunotherapy for Prostate Cancer

iSBTc 22nd Annual Meeting, Boston
November 4, 2007



Forward Looking Statements

This presentation includes forward looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward looking statements by their nature involve risks, uncertainties and assumptions inherent in discussing future events and trends. Information concerning risk factors that may affect such statements can be obtained in the Company's SEC filings.

Presenter Disclosure Information

David L. Urdal

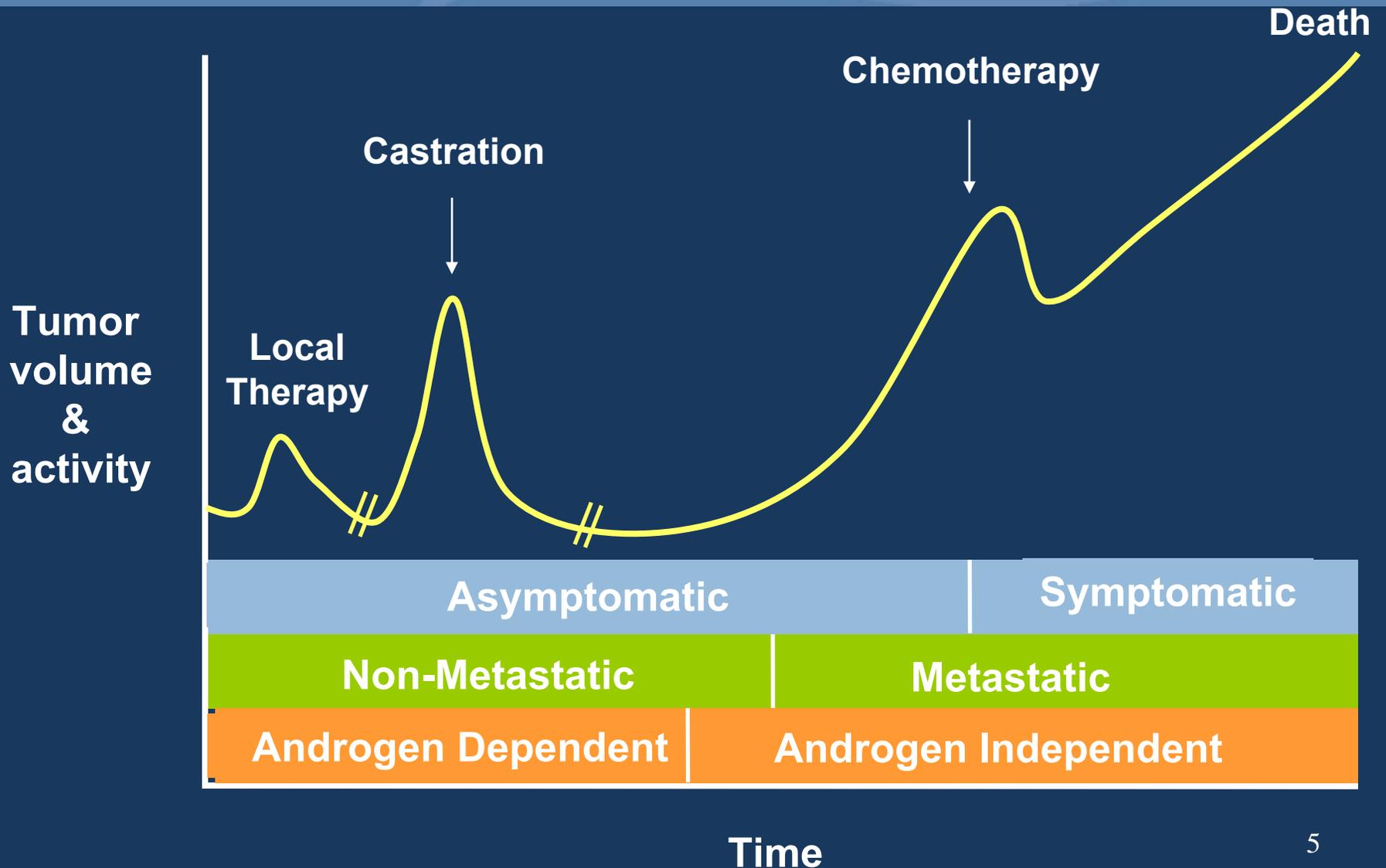
The following relationships exist related to this presentation:

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

The Sipuleucel-T Experience

- Introduction to Prostate Cancer and Sipuleucel-T
- Development
 - Clinical results
 - Regulatory milestones
- Conclusions

Natural History of Prostate Cancer



Androgen-Independent (Hormone-Refractory) Prostate Cancer Remains Unmet Medical Need

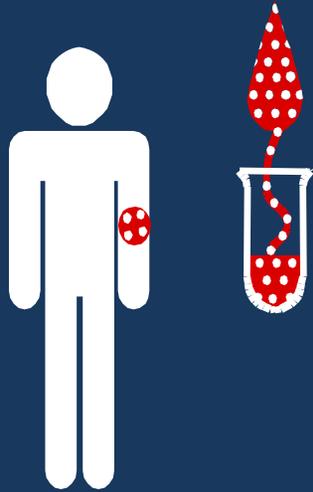
- Deadly disease
- Modest survival advantage seen with docetaxel-based regimens
- Majority of patients reject chemotherapy due to QOL impact
- Novel treatment approaches with acceptable safety profiles are needed

Sipuleucel-T

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

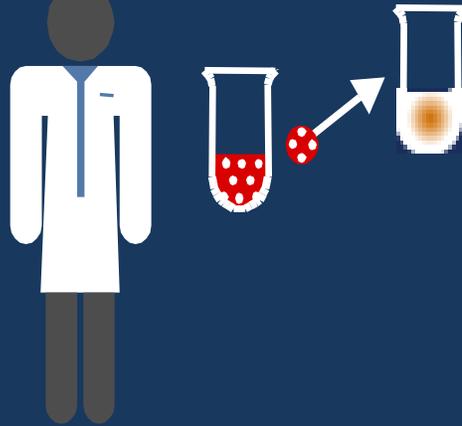
Sipuleucel-T: Patient-Specific Product

Day 1
Leukapheresis



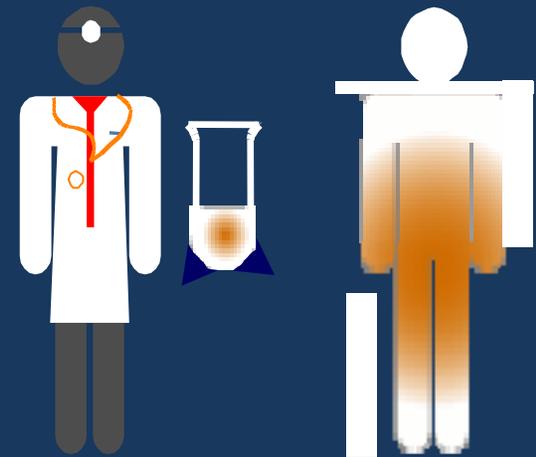
Apheresis Center

Day 2-3
sipuleucel-T is
manufactured



Dendreon

Day 3-4
Patient is infused



Doctor's Office

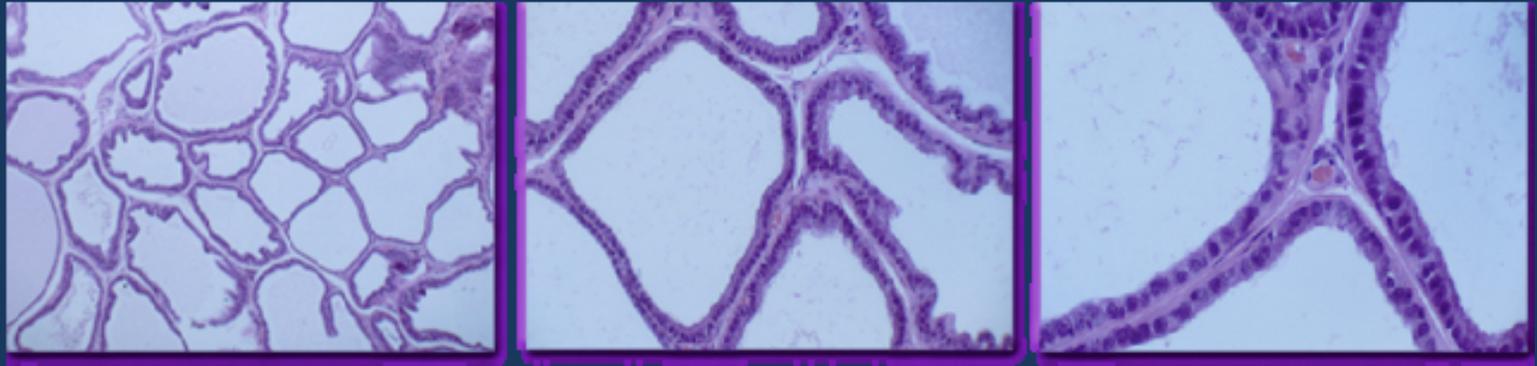
COMPLETE COURSE OF THERAPY:
Weeks 0, 2, 4

Pre-Clinical Rationale

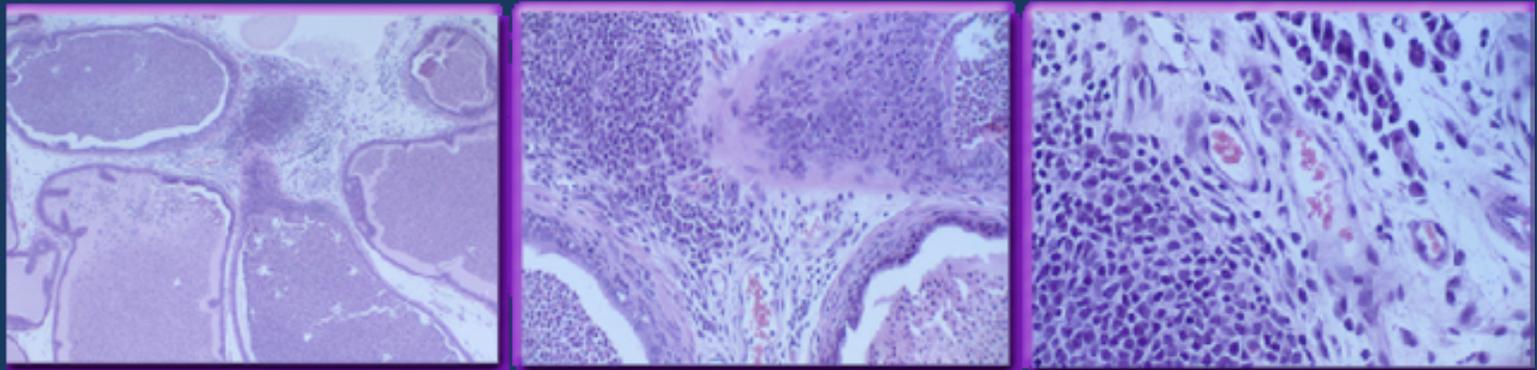
- Antigen-loaded APCs isolated from peripheral blood showed clinical promise in lymphoma
- Prostatic acid phosphatase (PAP) highly expressed in prostate tissue
- Granulocyte Macrophage Colony Stimulating Factor (GM-CSF) activates APCs
- Rat APCs, loaded with PAP+GM-CSF fusion protein, induced prostatitis

Sipuleucel-T is Active in a Preclinical Model of Autoimmune Prostatitis

Untreated

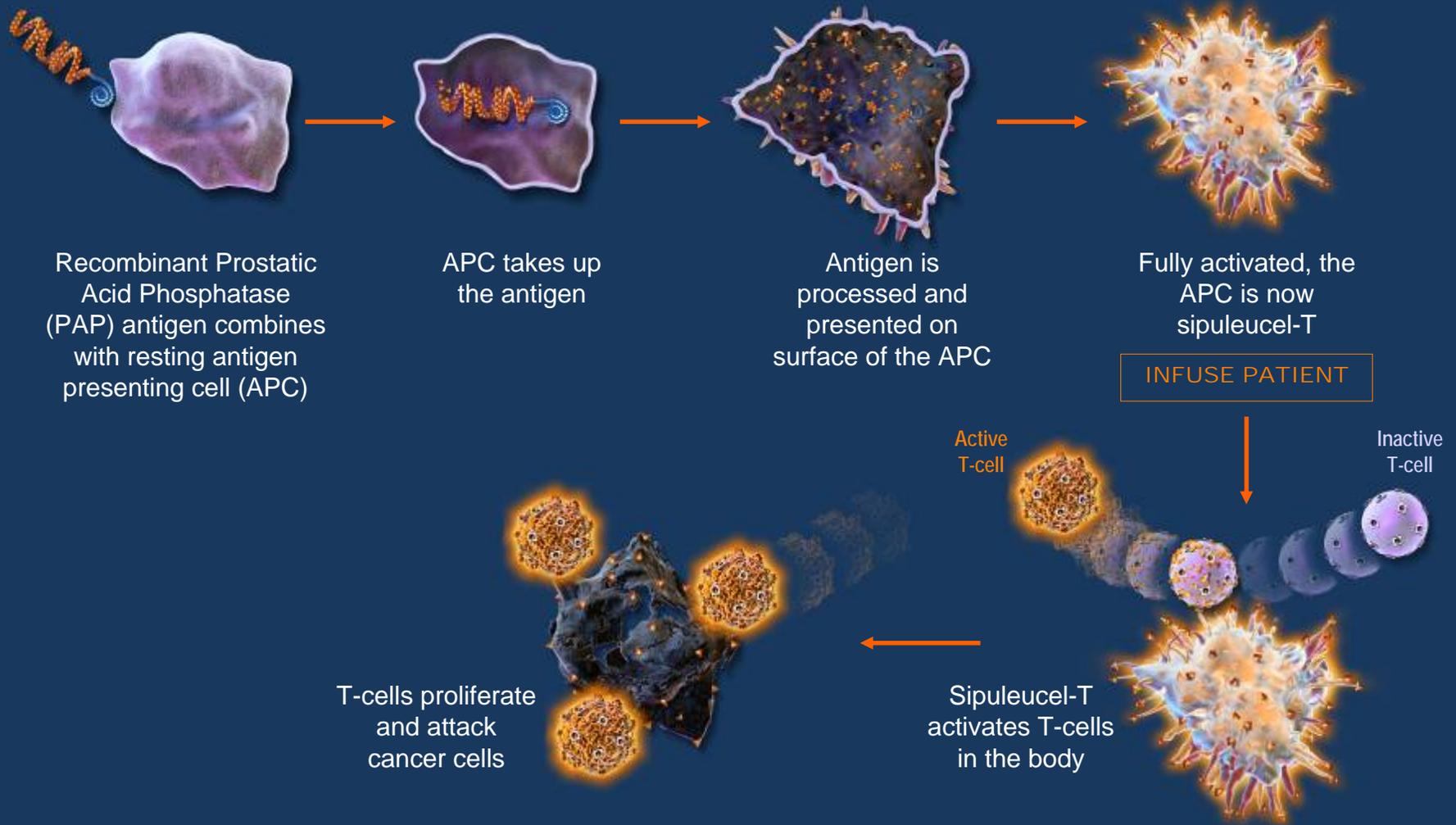


rProvenge-treated



Laus R et al. Cancer Res Therapy and Control 2001,11:1-10

Sipuleucel-T: autologous APC cultured with PAP-cytokine fusion protein



The precise mechanism of sipuleucel-T in prostate cancer has not been established.

Key Product Components and Attributes

- Mononuclear Cells
 - Total nucleated cell (TNC) count
 - CD54 positive cells take up antigen
 - CD54 positive cells present antigen to PAP specific T cells
 - CD54 upregulates during culture with antigen
- Recombinant Antigen
 - Specified concentration in culture
 - Manufactured under GMP conditions
 - Well characterized biologic

The Sipuleucel-T Experience

- Introduction to Prostate Cancer and Sipuleucel-T
- **Development**
 - Clinical results
 - Regulatory milestones
- Conclusions

Results: Sipuleucel-T Phases 1 & 2 Trials (Mayo Clinic and UCSF)

Safety

- No dose limiting toxicities
- Treatment well tolerated

Immune Responses

- Regimen: maximum immune responses reached after 3 infusions
- T cell responses were specific [not increased to recall flu antigen or KLH]

Small EJ, et al., J Clin Onc 2000;18:3894-3903

Phase 1 and 2 Trials-- Clinical Effects

- PSA decline of > 50% in 6/62 (10%) of AIPC_a patients
- Objective (bidimensional mass) response observed
- Immune responses correlated with prolonged time to objective progression
- Prolongs PSADT in ADPC

Burch PA, et al., *Clin Cancer Res* 6:2175, 2000

Small EJ, et al., *J Clin Oncol* 18:3894, 2000

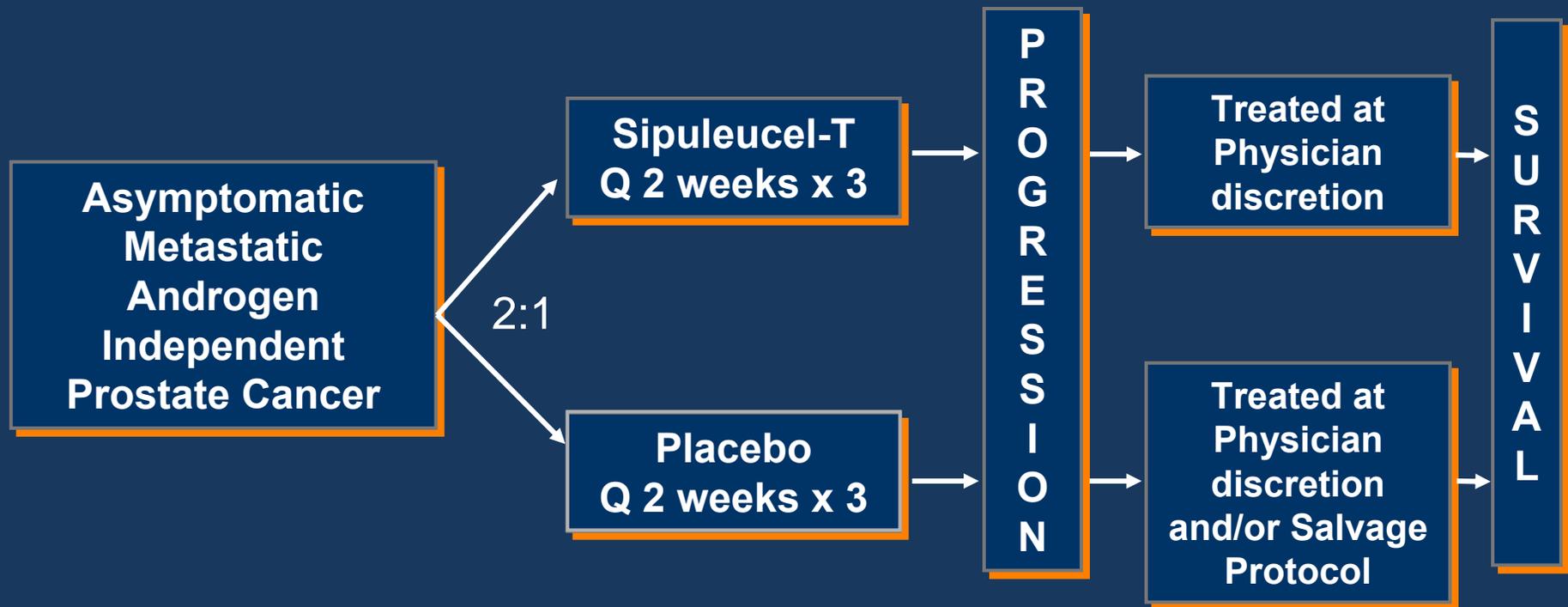
Burch PA, et al., *Prostate* 60:197, 2004

Rini BI, et al., *Cancer* 107: 67, 2006

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

Randomized, Double Blind, Placebo-Controlled Trials, Studies D9901 and D9902



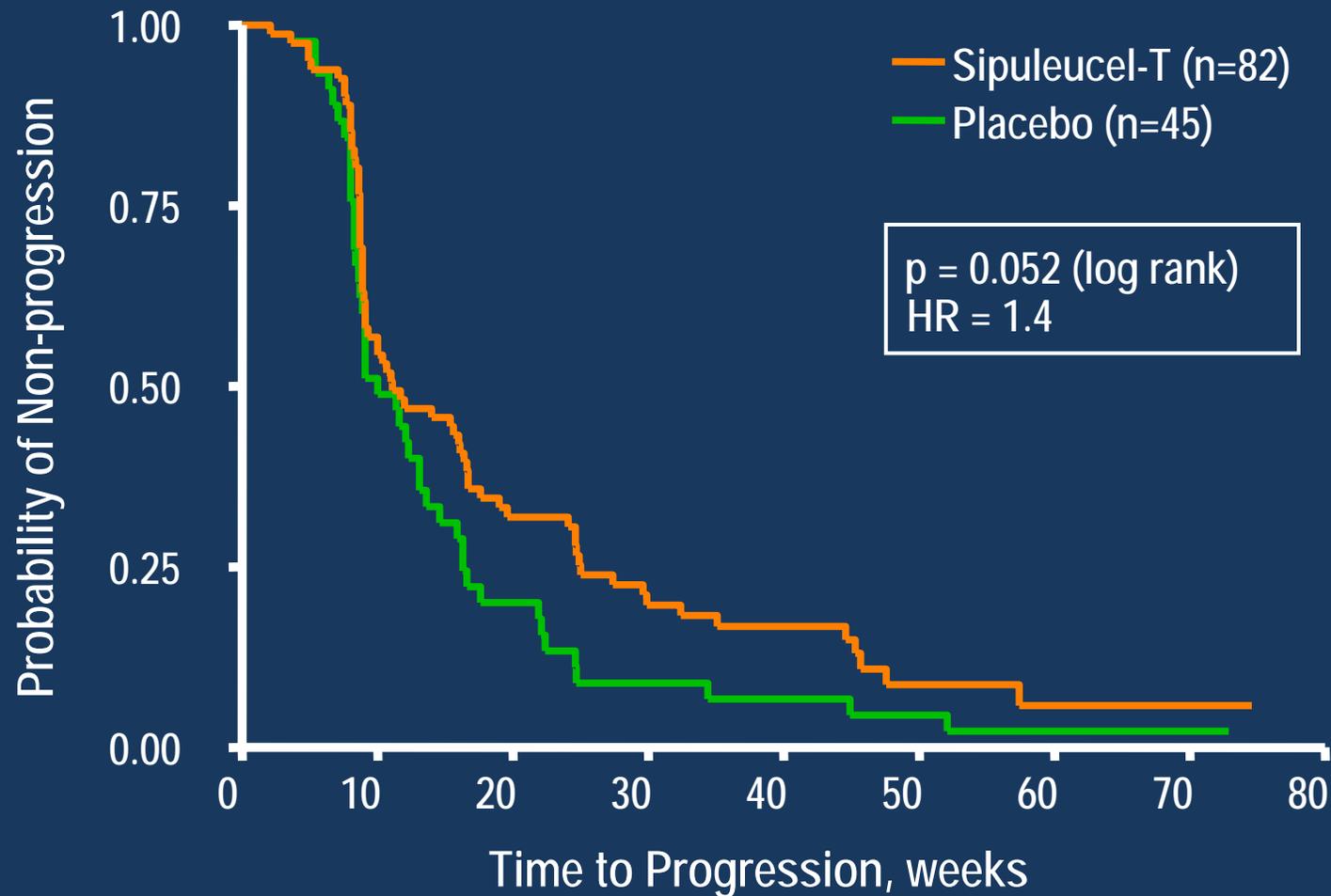
Primary endpoint: Time to Disease Progression

- Radiographic, Clinical or Pain
- Not PSA

Planned analysis: Overall Survival

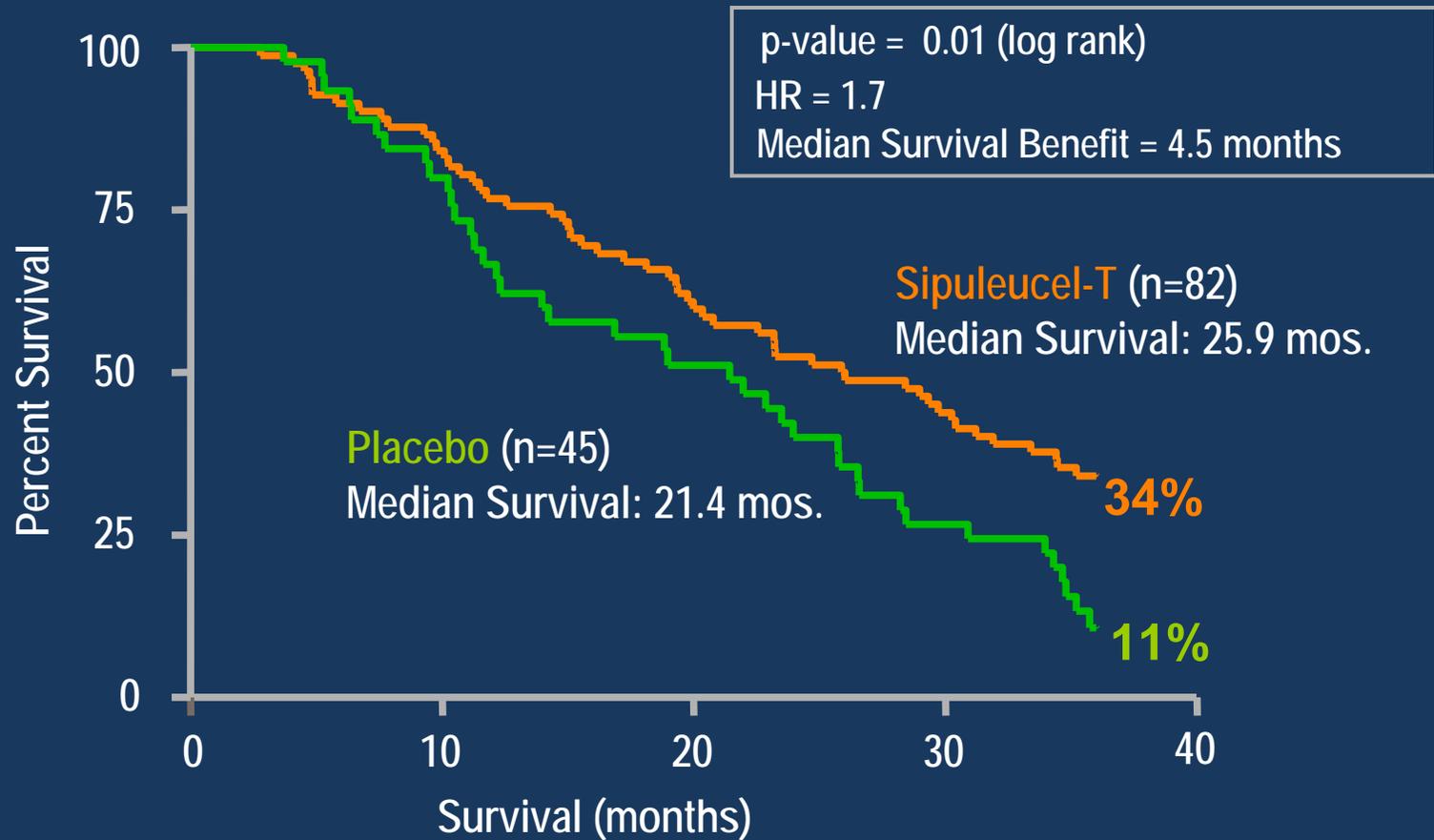
D9901 Primary Efficacy Analysis (ITT)

Time from Randomization to Disease Progression



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

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

Phase 3 Study Key Findings Study D9901

- 31% delay in time to progression
(p-value = 0.052; HR = 1.45)
- 41% overall reduction in risk of death
- Median survival benefit: 4.5 months
(p-value = 0.01; HR = 1.70)

Sensitivity Analyses to Test Survival Result Robustness

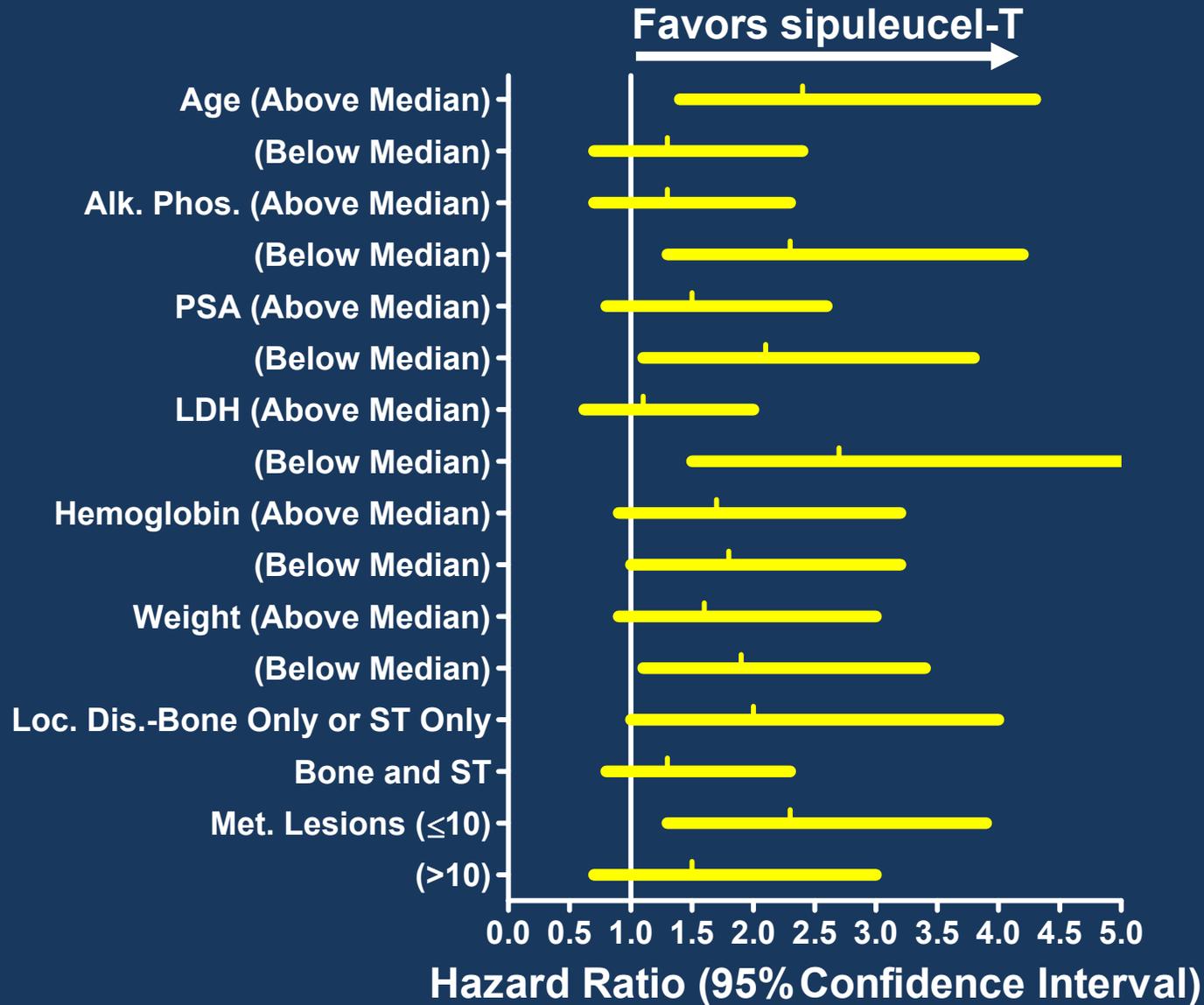
- Balance and consistency in study subpopulations
- Adjustment for baseline prognostic factors
- Assessment of chemotherapy use and timing following study treatment
- Prostate cancer-specific survival

Balance of Treatment Arms Halabi Analysis, Study D9901

Group	N	Predicted Survival (months) ⁺	Observed Survival (months)
Sipuleucel-T	82	20.1	25.9
Placebo	45	19.9	21.4

+ Median of predicted survivals, as calculated using model of Halabi et al., *JCO* 2003

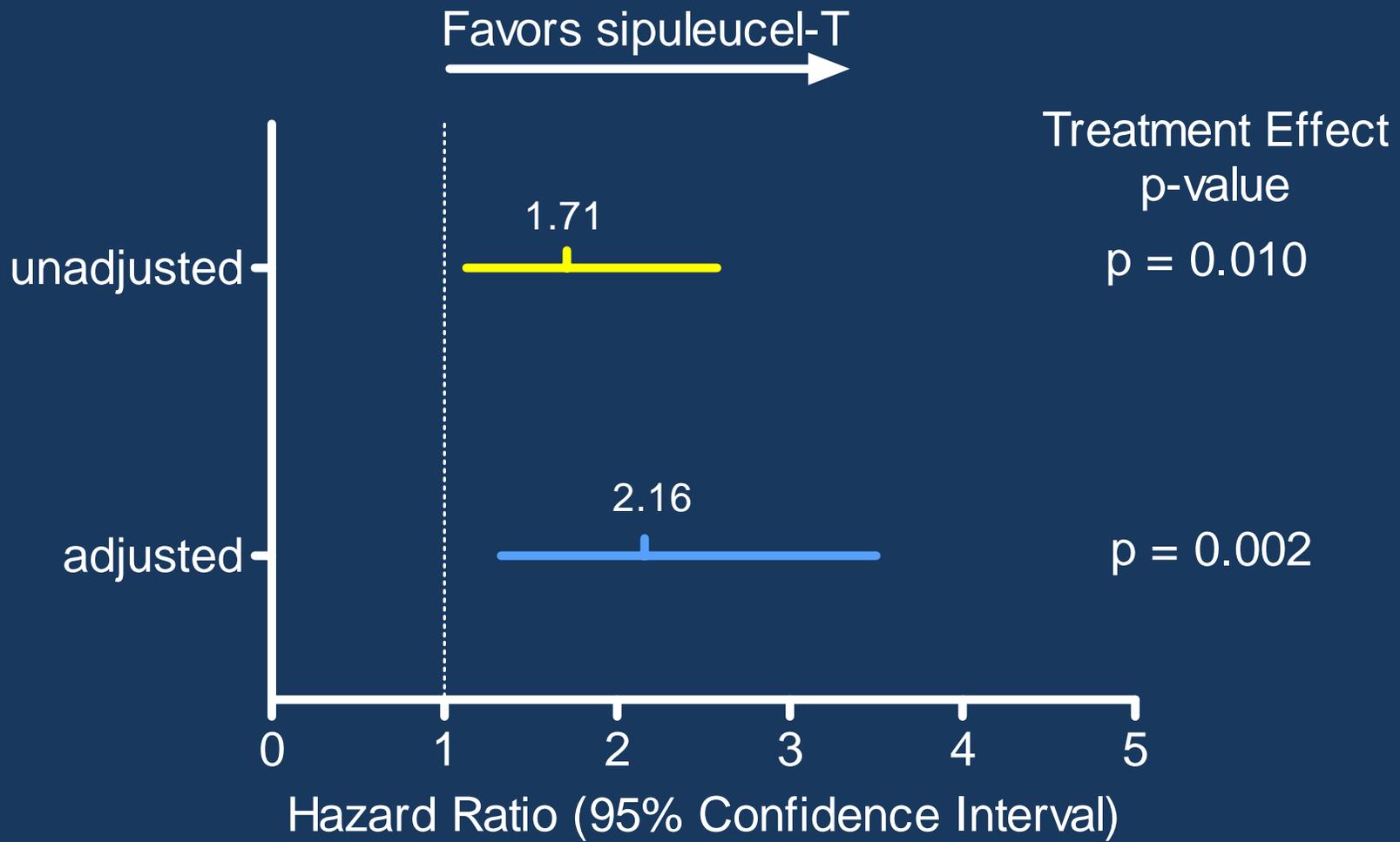
Treatment Effect Consistent Across Subpopulations



Adjustment for Multiple Prognostic Factors

- LDH
- PSA
- # bone metastases
- Weight
- Localization of disease

Survival Benefit Confirmed by Adjustment for Multiple Prognostic Factors



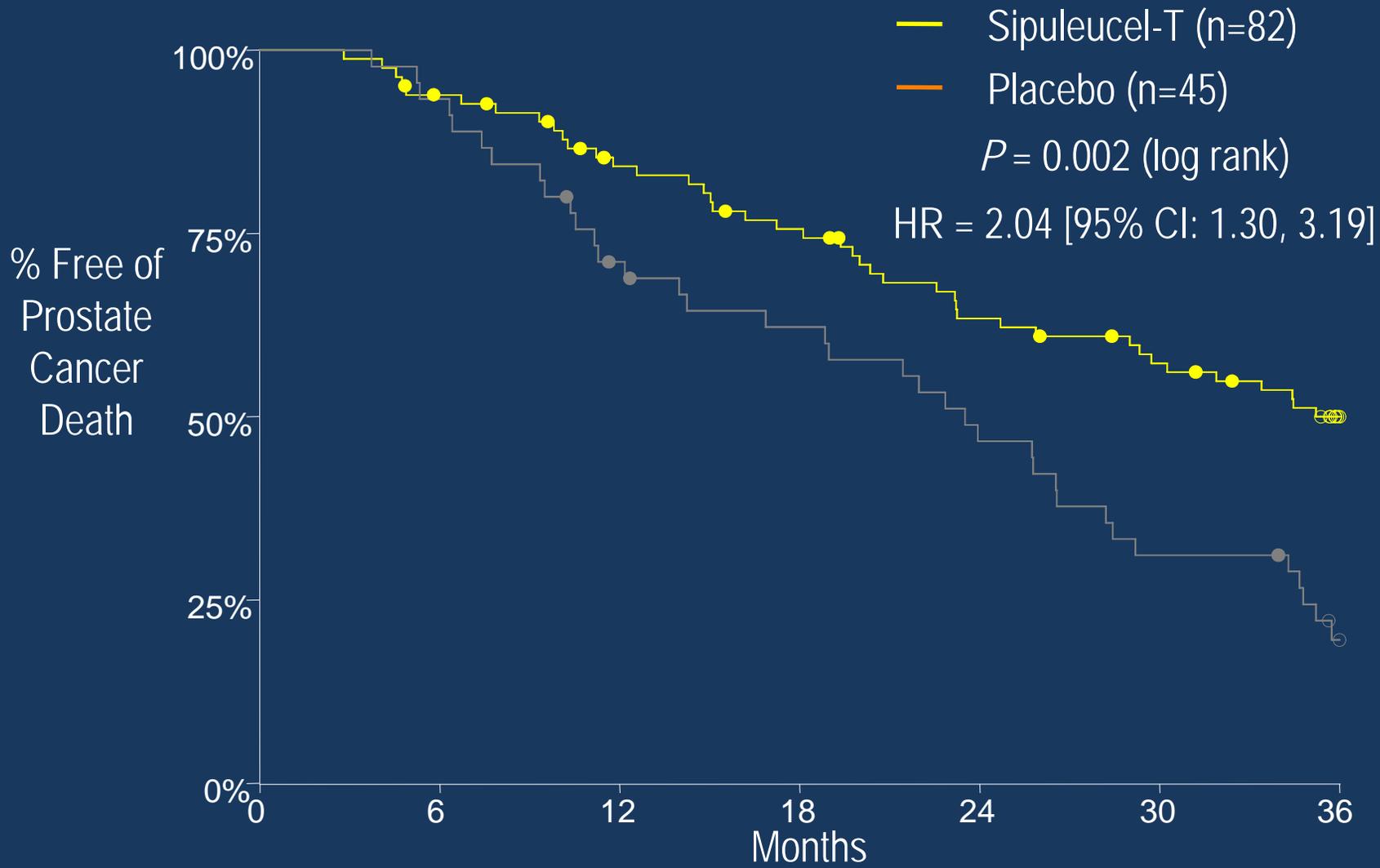
Chemotherapy Use Following Study Treatment Does Not Explain Survival Benefit

- No evidence of a difference in docetaxel use

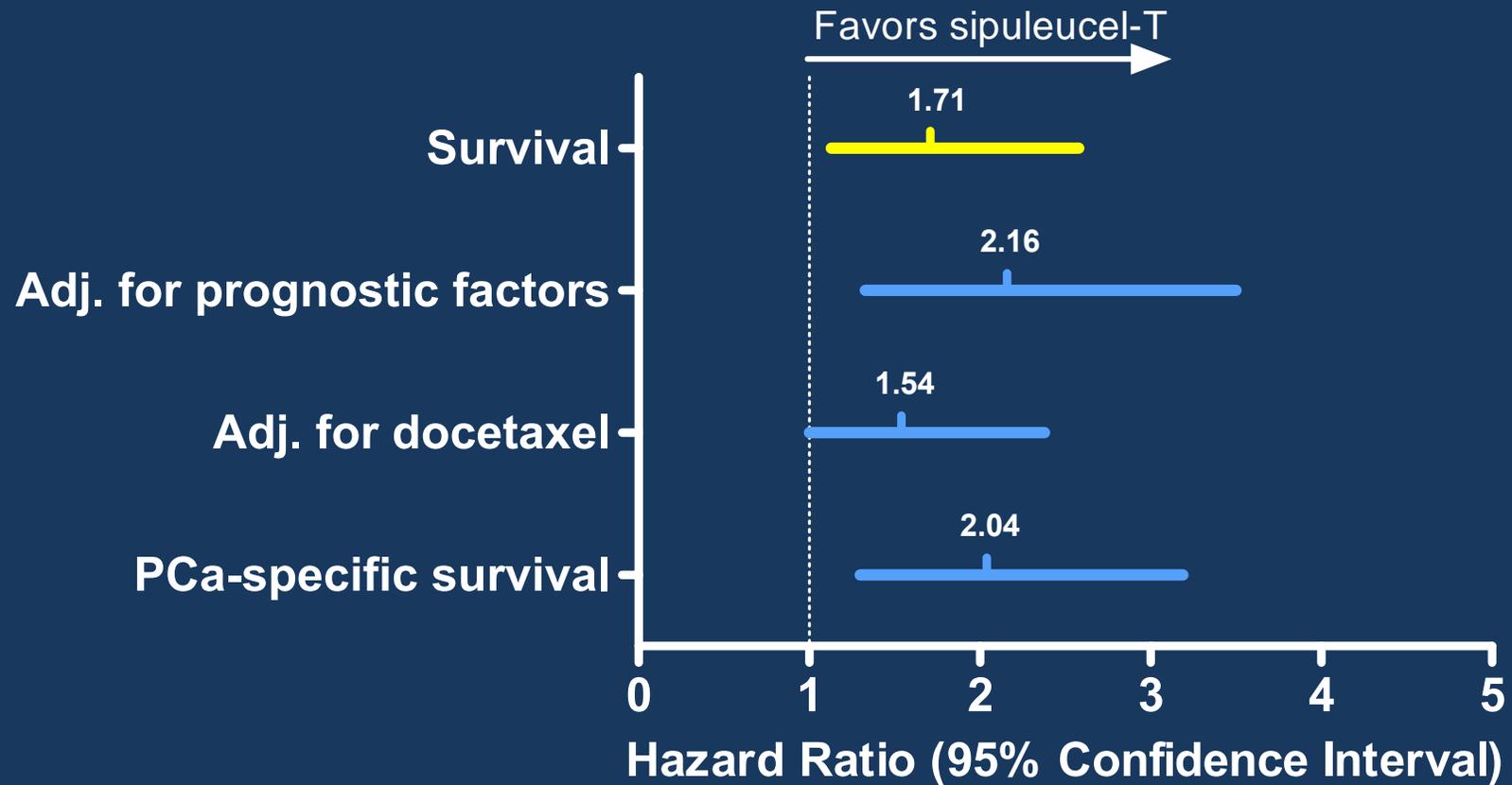
	<u>sipuleucel-T</u>	<u>placebo</u>
– Chemotherapy	56%	63%
– Docetaxel	37%	49%

- No evidence of a delay in time to docetaxel initiation in placebo arm
- Treatment effect remained strong:
 - In study subpopulations based on docetaxel use
 - After adjustment for docetaxel use

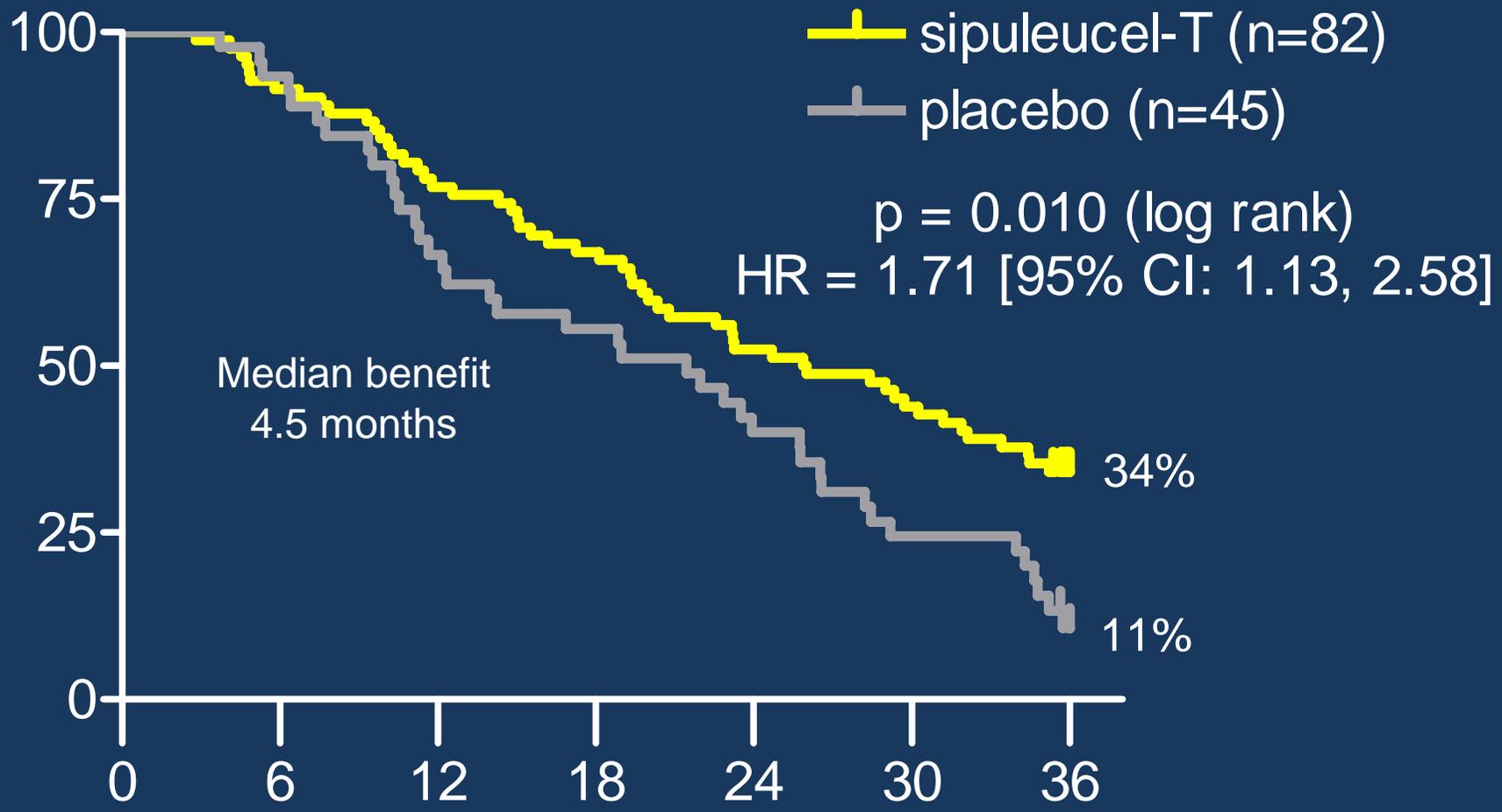
Prostate Cancer Specific Survival Study D9901



Survival Results Confirmed by Multiple Sensitivity Analyses



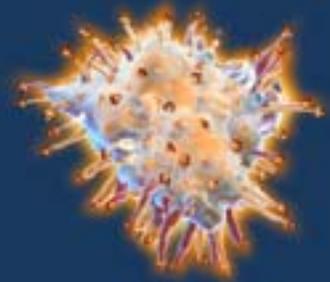
Clinically Significant and Statistically Persuasive Overall Survival Benefit



Sipuleucel-T Laboratory/Clinical Correlations

Key product attributes:

- Total nucleated cell count
- CD54 count
- CD54 'upregulation'



Fully activated, the APC is now sipuleucel-T

INFUSE PATIENT

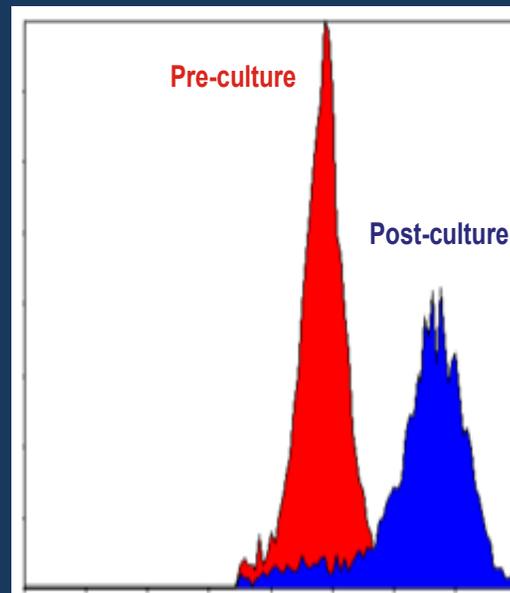
Active T-cell

Inactive T-cell

Sipuleucel-T activates T-cells in the body

The precise mechanism of sipuleucel-T in prostate cancer has not been established.

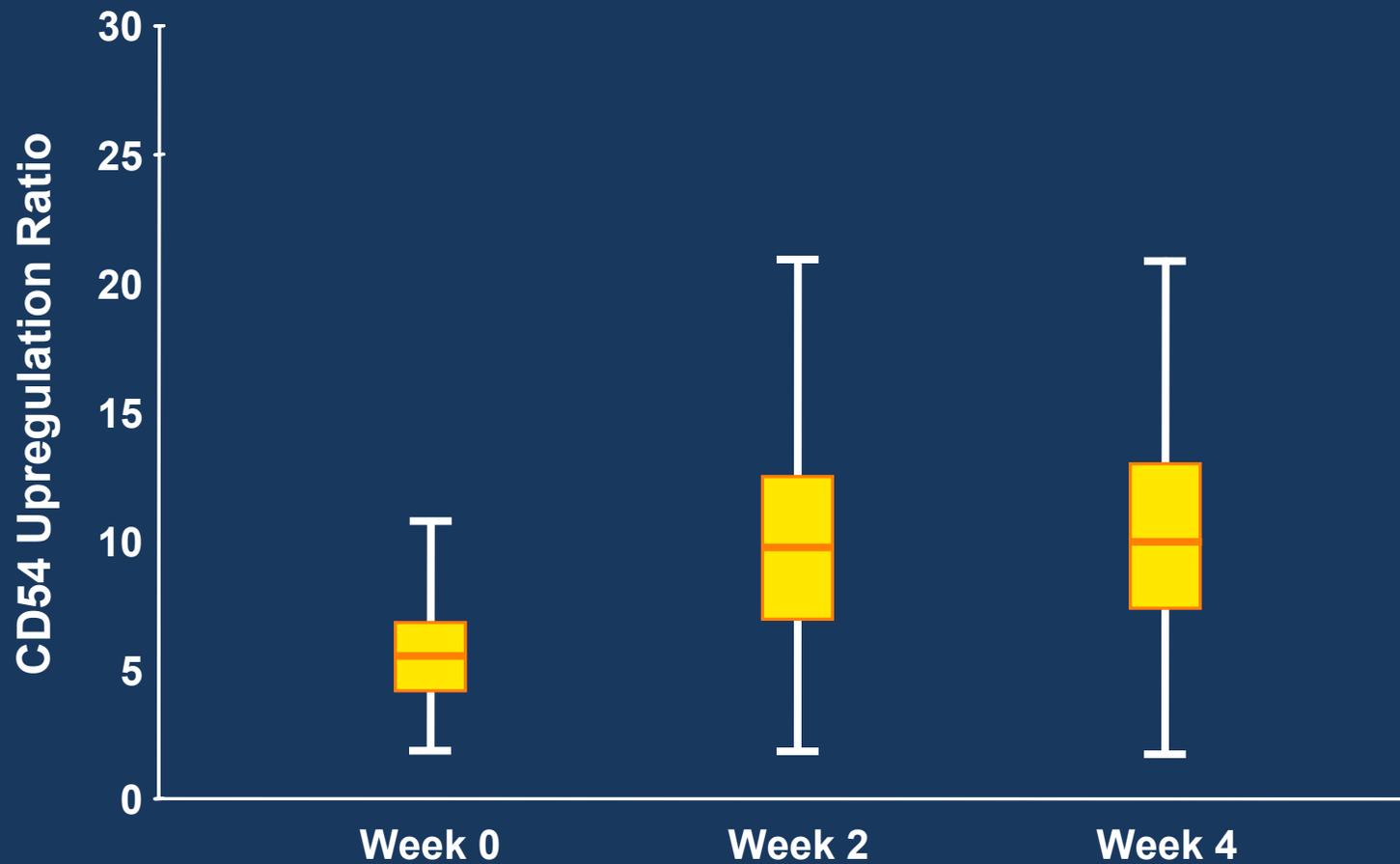
CD54 Upregulation Potency Assay for APCs



Mean Fluorescence
Intensity

CD54 Upregulation by Treatment Week

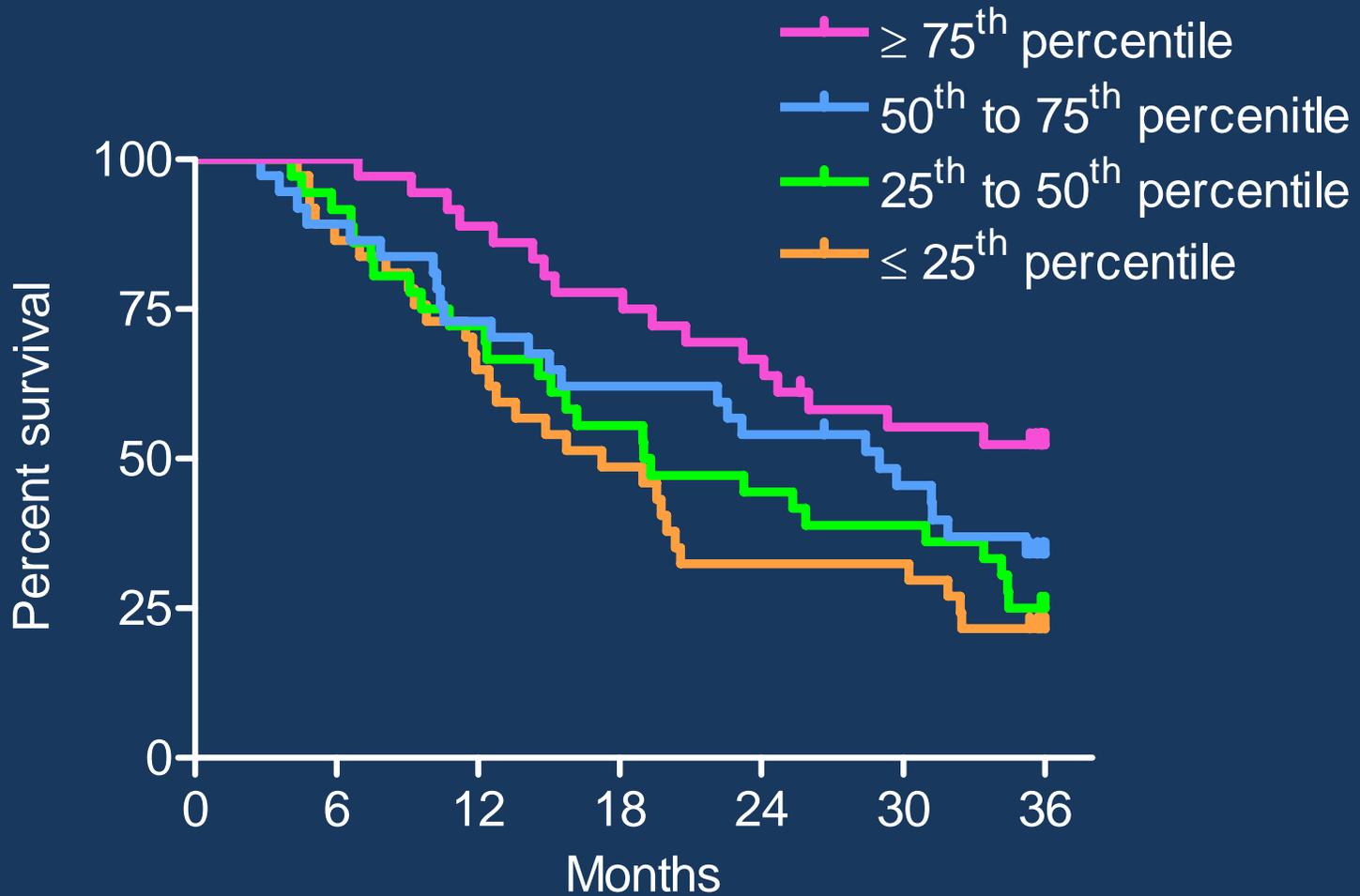
Phase 3 Manufacturing Data



Correlation Analysis for Key Product Attributes and Survival, Integrated Studies 1 & 2

Variable	p-value N = 146
CD54 Upregulation	0.009
Total Nucleated Cells	0.018

Survival by Cumulative CD54 Upregulation in Quartiles, Integrated Studies 1 & 2



Correlation analysis for Key Product Attributes and Survival

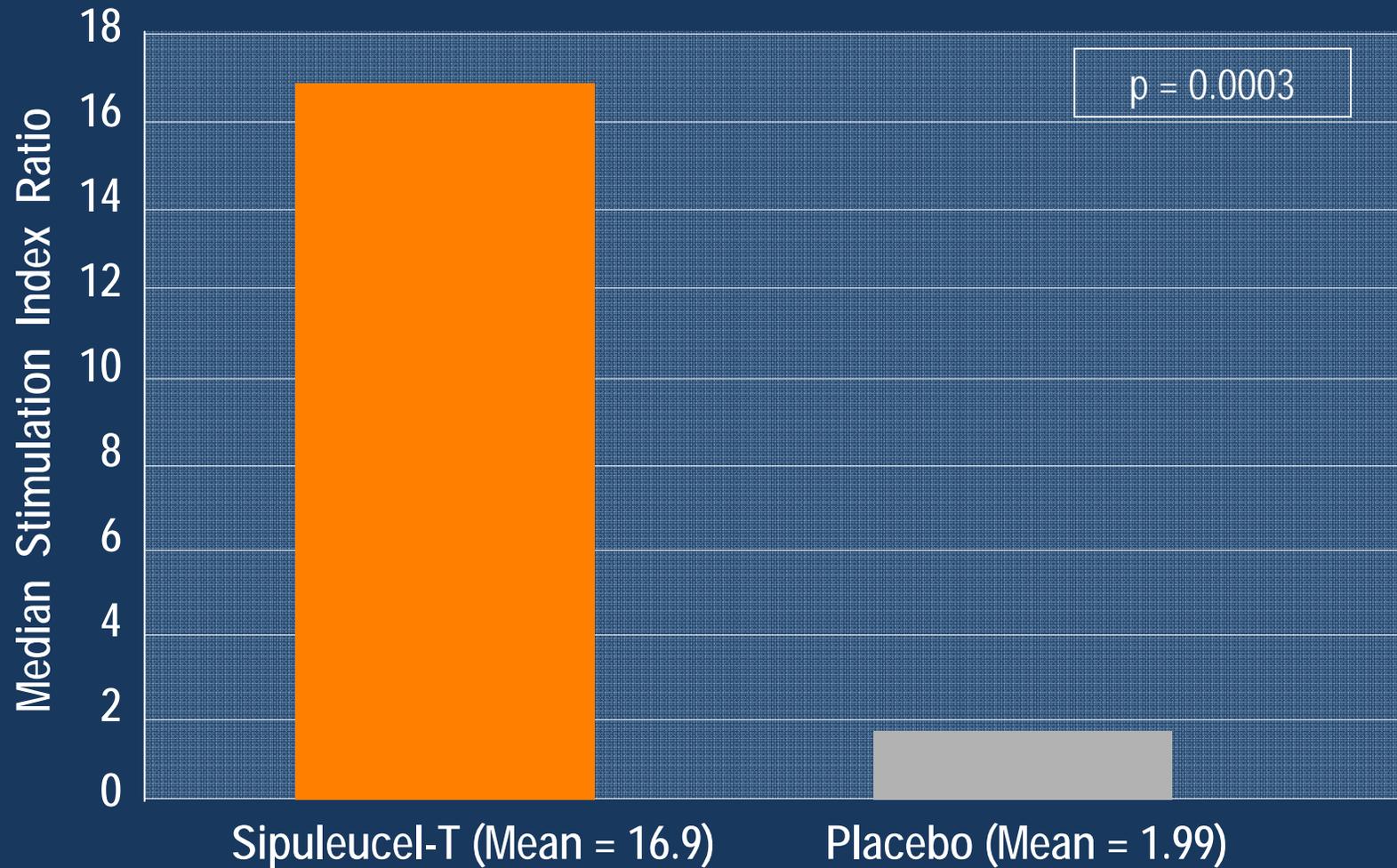
Variable	Unadjusted p-value N = 146	p-value with Adjustment* N = 134
CD54 Upregulation	0.009	0.022
Total Nucleated Cells	0.018	0.138

*Adjusted for 5 prognostic factors in Cox regression model

Sipuleucel-T Potency Correlates with Survival

- Biologically relevant product measurement
- Independent of prognostic factors
- May support the efficacy findings

Sipuleucel-T Induces Significant T-cell Mediated Immune Response (Week 0 to Week 8)



Sipuleucel-T is Well Tolerated

Event [n(%)]	Sipuleucel-T (n=82)		Placebo (n=45)		p-value
	Grade 1-2	Grade 3-4	Grade 1-2	Grade 3-4	
Rigors (chills)	45 (54.9)	4 (4.9)	4 (8.9)	0 (0.0)	<0.001
Pyrexia (fever)	22 (26.8)	2 (2.4)	1 (2.2)	0 (0.0)	0.0001
Tremor	8 (9.8)	0 (0.0)	0 (0.0)	0 (0.0)	0.0497
Feeling Cold	7 (8.5)	0 (0.0)	0 (0.0)	0 (0.0)	0.0505

The Sipuleucel-T Experience

- Introduction to Sipuleucel-T process and characterization
- Development
 - Clinical results
 - Regulatory milestones
- Conclusions

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

Regulatory Milestones

- The Center for Biologics Evaluation and Research (CBER)
 - Office of Cellular, Tissue and Gene Therapies (OCTGT)
- September 2005: Pre-BLA Meeting held with FDA:
 - 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 sipuleucel-T
- November 2005: FDA granted Fast Track Status for sipuleucel-T

Regulatory Milestones (continued)

- August – November 2006: Submit rolling BLA
- January 2007: BLA accepted for Priority Review
- March 2007: FDA's Cell, Tissue and Gene Therapies Advisory Committee

Cell, Tissue and Gene Therapy Advisory Committee

- 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

Sipuleucel-T Studies in Prostate Cancer



	Early Stage Androgen Dependent			Advanced Stage Androgen Independent		
Study	D9905	P-16	P-11	D9901	D9902A	D9902B
Phase	Phase 2	Phase 2	Phase 3	Phase 3	Phase 3	Phase 3
No. of Subjects	19	22	~175	127	98	500
Results	Sipuleucel-T may lead to improved PSADT Increase in median PSADT of 51%	Sipuleucel-T plus Avastin™ increased PSADT Increase in median PSADT of 85%	Data suggest a potential role for sipuleucel-T in ADPC Increase in median PSADT of 35% (P = 0.046)	4.5 month median survival benefit for men who received sipuleucel-T	3.3 month median survival benefit for men who received sipuleucel-T	Patient accrual complete in 2007
Complete	✓	✓	Preliminary	✓	✓	Enrolled

IMPACT Phase 3 Study (D9902B)

IMmunotherapy for Prostate AdenoCarcinoma Treatment

- Randomized 2:1, double-blind, placebo-controlled
- ~500 men with minimally symptomatic, metastatic AIPC
- Enrolling at ~70 sites in North America
- Primary endpoint: Survival
- Secondary endpoint: Time to objective disease progression
- Special Protocol Assessment
- Positive interim or final survival analysis sufficient to amend BLA

Sipuleucel-T Phase 3 Study: Conclusions

- An ITT analysis of survival demonstrated that compared with Placebo, sipuleucel-T:
 - Provided a survival advantage of 4.5 months
 - Resulted in a significantly greater percentage of patients alive at 36 months (34% vs 11%)
- There is a trend towards improved median time to progression in asymptomatic AIPC patients treated with sipuleucel-T, compared with placebo ($P = 0.052$, Hazard Ratio = 1.45)

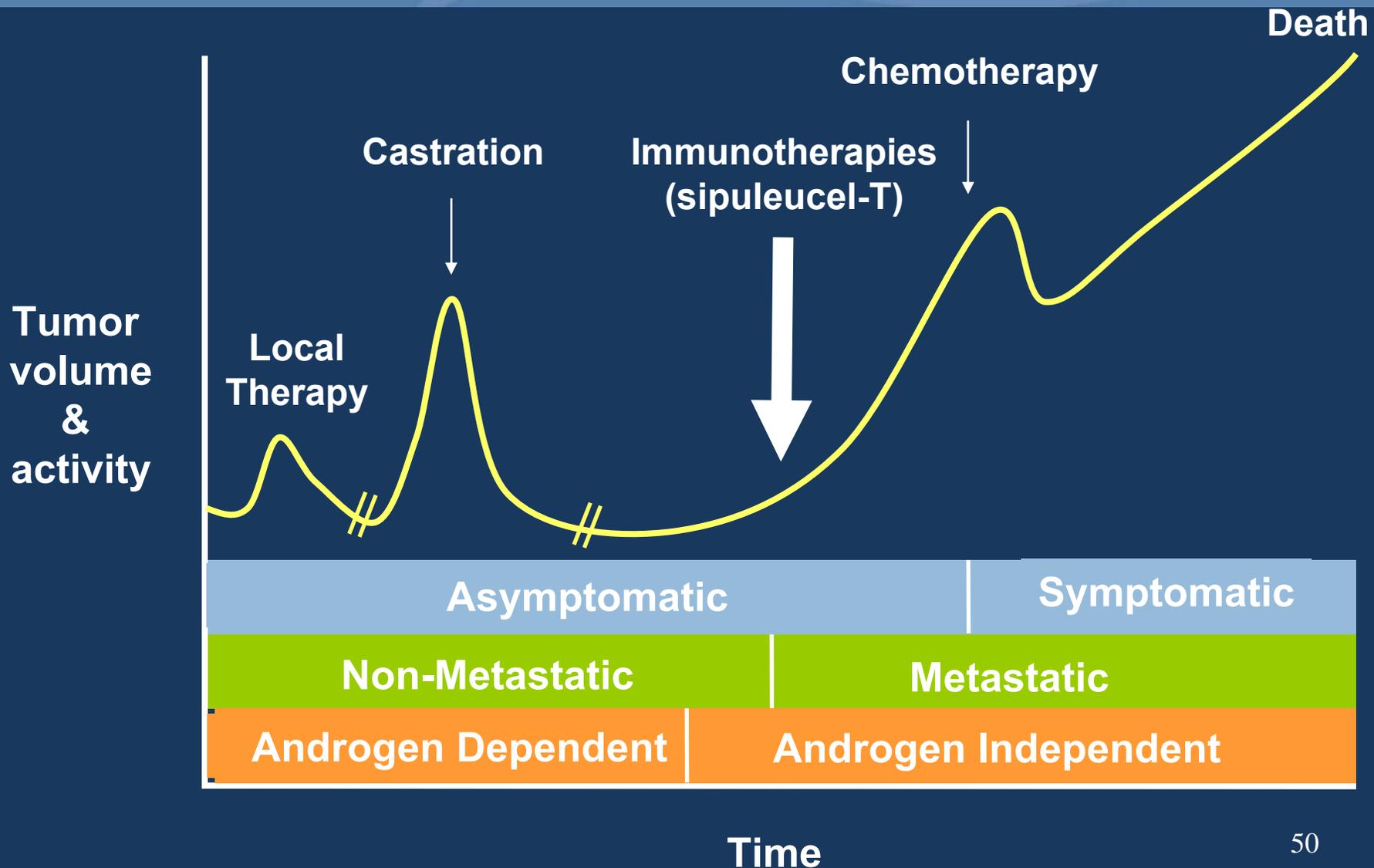
Sipuleucel-T Phase 3 Study: Conclusions

- Survival results represent mature data set
- Survival data not explained by differences in:
 - Non-prostate cancer related deaths
 - Imbalance in baseline prognostic factors
 - Subsequent chemotherapy use or timing following treatment
- Potency may correlate with survival outcome
- Consistent results between studies

Sipuleucel-T Phase 3 Study: Conclusions

- Rapid tumor progression prior to onset of immune effect may explain discordance between effect of sipuleucel-T on time to progression and its effect on overall survival
- TTP may not be the most appropriate endpoint for clinical studies in patients treated with immunotherapy agents like sipuleucel-T
- Sipuleucel-T is well tolerated and has a favorable toxicity profile
- Sipuleucel-T results in a significant T cell mediated immune response
- Sipuleucel-T represents the first non-chemotherapeutic agent that may provide a survival advantage in AIPC patients

Active Cellular Immunotherapy: A Potential New Treatment for Prostate Cancer



Acknowledgements

- Paul F. Schellhammer, MD – Eastern Virginia Medical Center, Norfolk, VA
- Patrick A. Burch, MD - Mayo Clinic & Foundation
- Celestia Higano, MD – Seattle Cancer Care Alliance, Seattle, WA
- Eric J. Small, MD – UCSF Comprehensive Cancer Center, San Francisco, CA
- Charles Redfern, MD – Sharp Health Care, San Diego, CA
- James Arseneau, MD – Albany Regional Cancer Center, Albany, NY
- Sebastian George, MD – Cancer & Blood Institute, Palm Desert, CA
- John Nemunaitis, MD – US Oncology, Dallas, TX
- Richard J. Rosenbluth, MD – Hackensack University Medical Center, Hackensack, NJ
- Wayne Poll, MD – AKSM Clinical Research Corp, Columbus, OH
- Steven P. Anthony, MD – Cancer Care Northwest, Spokane, WA

Dendreon Staff:

Frank Valone, M.D., Jelle Kylstra, M.D., Reiner Laus, M.D., Elizabeth Smith, M.V. Peshwa, Ph.D., Lori Jones, Ph.D., Israel Rios, M.D., Robert Hershberg, M.D., Mark Frohlich, M.D., Nicole Provost, Ph.D.