

PROVENGE[®] (sipuleucel-T)

**Cellular, Tissue, and Gene Therapies
Advisory Committee Meeting**

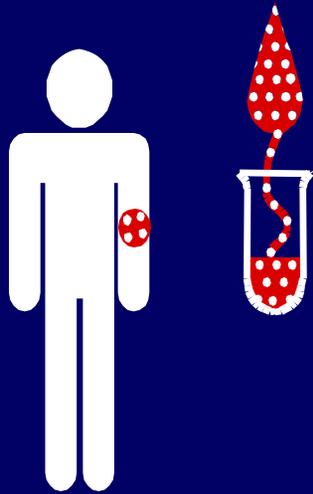
March 29, 2007

sipuleucel-T

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

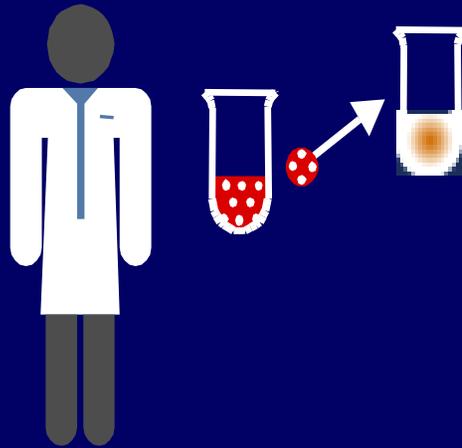
Sipuleucel-T: Patient-Specific Product

Day 1
Leukapheresis



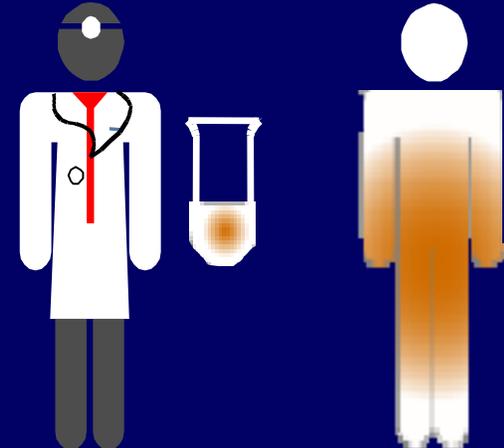
Apheresis Center

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

Clinical Development Program of Sipuleucel-T

Phase 1 & 2

AIPC

Study 9610
Study 9702
Study D9801
Study D9903
Study PB01

ADPC

Study D9905

Phase 3 Completed

AIPC

**Study 1
(Protocol D9901)**

**Study 2
(Protocol D9902A)**

Phase 3 Ongoing

AIPC

**Study 3
(Protocol D9902B)**

ADPC

Study P-11

Regulatory History of Phase 3 Program

- 1999/2000**
 - Studies 1 & 2 initiated
 - Primary endpoint: TTP
 - 36 month follow up for survival planned
 - Safety

- 2002**
 - Study 1 analyzed for primary endpoint
 - Statistical significance not observed for TTP
 - Study 2 enrollment stopped (blind maintained)
 - Survival follow up for Studies 1 & 2 continued

- 2003**
 - Study 3 initiated under SPA (results in 2010)

- 2004/2005**
 - 36 month follow up for all subjects completed
 - Study 1 overall survival benefit in ITT
 - Study 2 trend in overall survival in ITT
 - Fast Track designation

- 2006**
 - File BLA
 - Priority Review

Sipuleucel-T Proposed Basis for Licensure

- **Randomized, double blind, placebo-controlled studies**
- **Primary Evidence: Study 1**
 - **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 Study 2**
 - **Integrated analyses**
 - **Survival correlates with product potency**
- **Demonstrated safety and tolerability**

Proposed Indication for Sipuleucel-T

PROVENGE (sipuleucel-T) is indicated for the treatment of asymptomatic, metastatic, androgen independent prostate cancer

Agenda

Introduction

Elizabeth Smith

**Clinical Development,
Efficacy, and Safety**

Mark Frohlich, MD

**Development History and
Key Product Attributes**

Nicole Provost, PhD

Clinical Practice

Christopher Logothetis, MD

Benefits & Risks

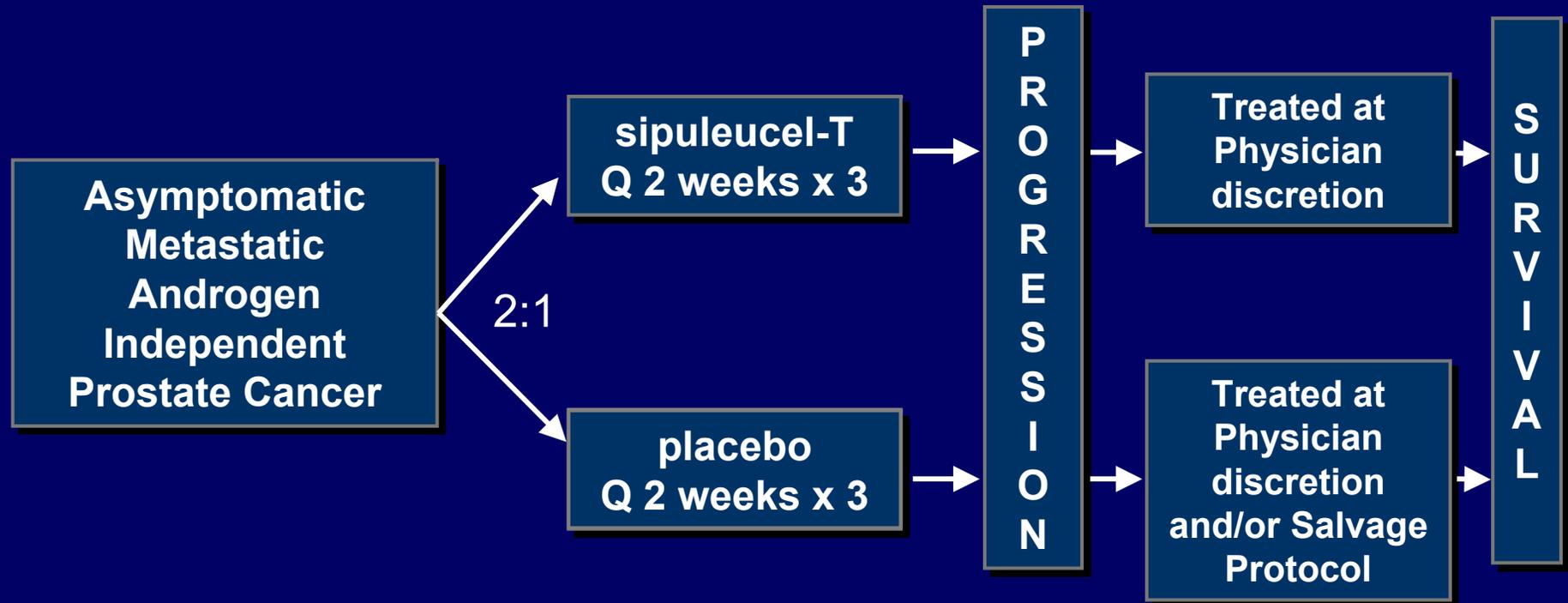
Elizabeth Smith

Clinical Development and Efficacy

Mark Frohlich, MD

Vice President, Clinical Affairs

Randomized, Double Blind, Placebo-Controlled Trials, Studies 1 & 2



Primary endpoint: Time to Disease Progression
Planned analysis: Overall Survival

Statistical Methods

- **Time to Disease Progression**
 - Intent to treat (ITT): all patients randomized
 - Kaplan-Meier estimates
 - Log rank (2-sided p-values)
 - Hazard ratio from Cox regression model
- **Overall Survival**
 - Planned efficacy analysis at 36 months of follow-up
 - Kaplan-Meier estimate
 - Survival rates at 3, 6, 9, 12, and every 6 months thereafter
 - Cox regression model
 - P-value based on log rank

Major Eligibility Criteria Studies 1 & 2

- **Metastatic prostate cancer**
- **No visceral metastases**
- **Tumor progression despite androgen deprivation (consensus criteria)**
- **No cancer-related pain**
- **No systemic steroids or prior immunotherapy**
- **ECOG 0 or 1**

Study 1

Baseline Characteristics & Lab Values Study 1

Characteristic	sipuleucel-T (n = 82)	placebo (n = 45)
Median age, years (range)	73 (47 – 85)	71 (50 – 86)
Median weight, lbs	194.1	186.5
ECOG 0, %	75.6	82.2
Ethnicity: Caucasian, %	89.0	93.3
Median PSA, ng/mL	46.0	47.9
Median PAP, ng/mL	7.0	6.5
Median alk phos., U/L	102.0	92.0
Median hemoglobin, g/dL	13.0	13.1
Median LDH, U/L	173.5	172.0
Prior chemotherapy use, % yes	3.7	8.9

Baseline Disease Parameters Study 1

Characteristic	sipuleucel-T (n = 82)	placebo (n = 45)
Tumor Differentiation (%)		
Gleason score ≤ 7	61.0	55.6
Gleason score > 7	39.0	44.4
Disease Location, (%)		
Bone only	42.0	23.8
Soft tissue only	6.2	7.1
Bone and soft tissue	51.9	69.0
Number of Bone Metastases per patient, (%)		
≤ 10	58.5	73.3
> 10	41.5	26.7

Independent Prognostic Model Predicts Treatment Arm Balance and Supports Treatment Effect Study 1

Group	N	Predicted Survival (months) ⁺
sipuleucel-T	82	20.1
placebo	45	19.9

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

Time to Disease Progression Endpoint

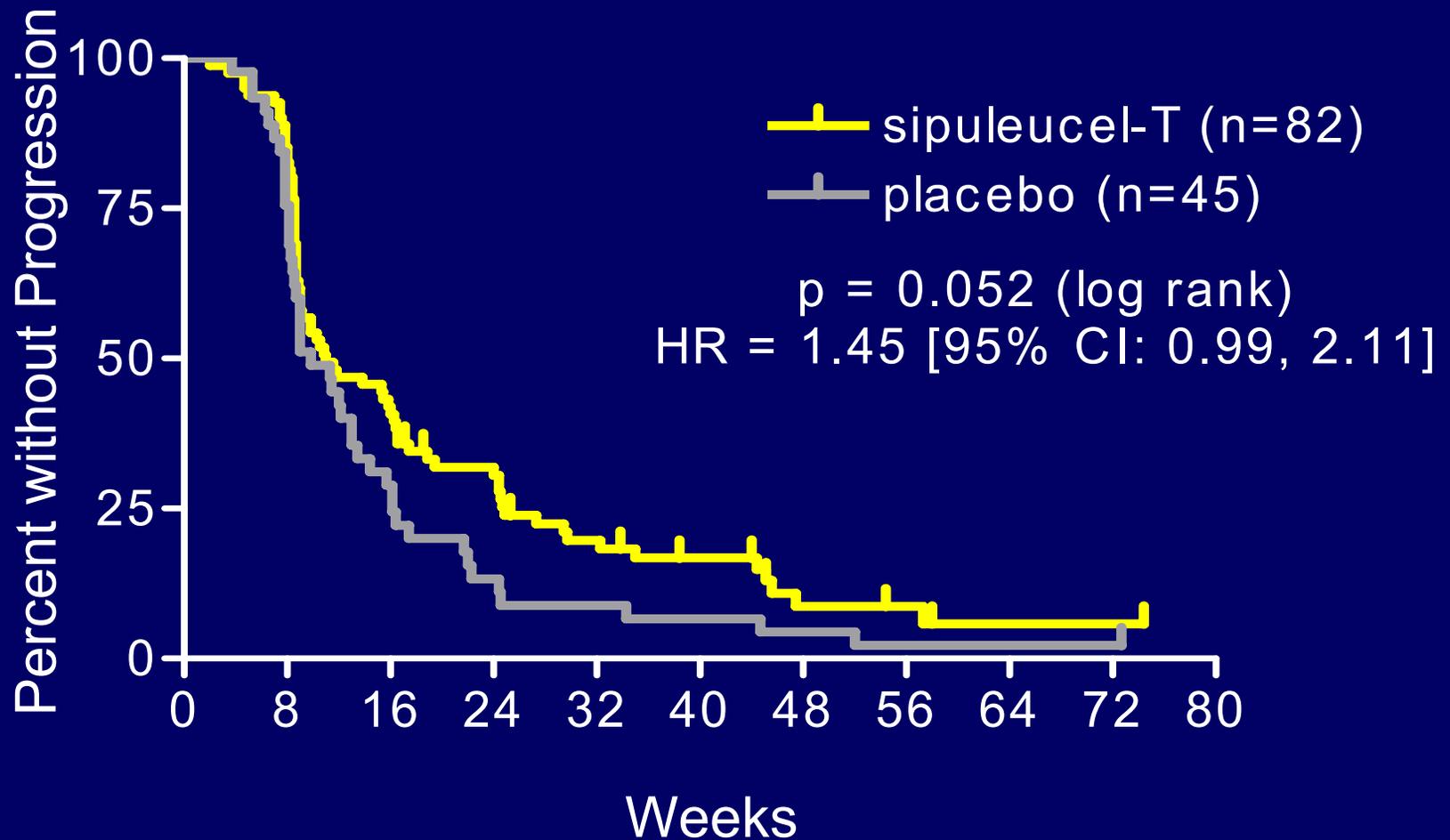
- **Definition**

- Radiographic progression
- Clinical progression
- Pain progression
- *Not* PSA progression

- **Assumptions**

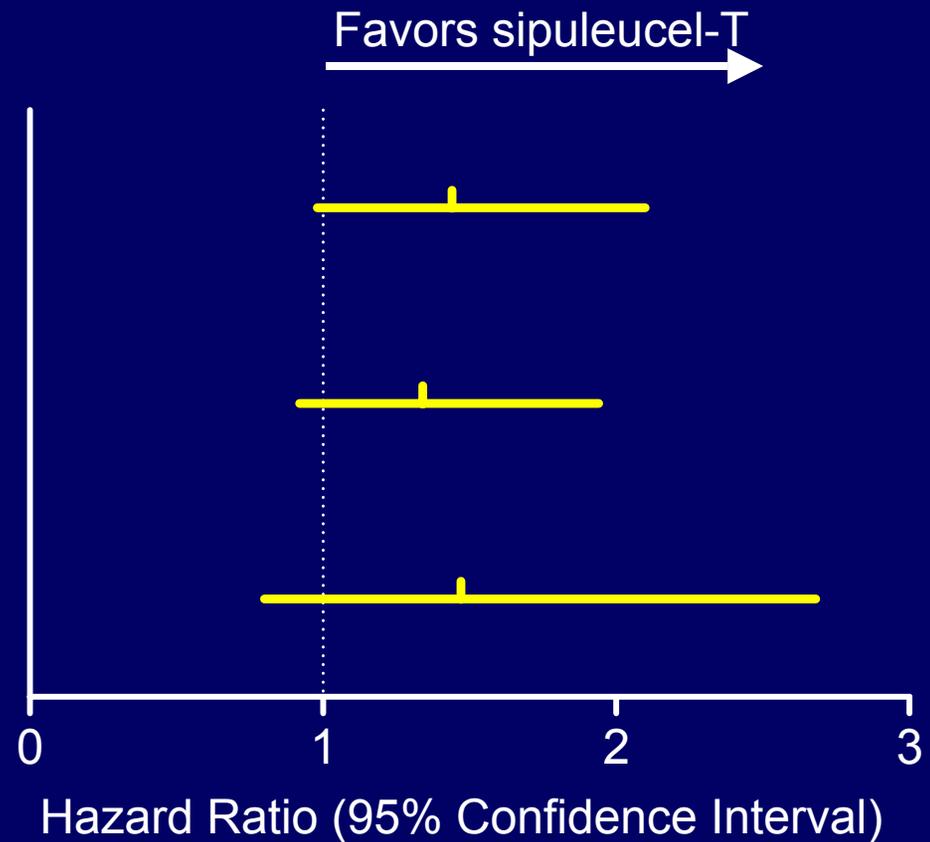
- Median time to disease progression
 - placebo: 16 weeks
 - sipuleucel-T: 31 weeks
- HR 1.925

Time to Disease Progression Study 1



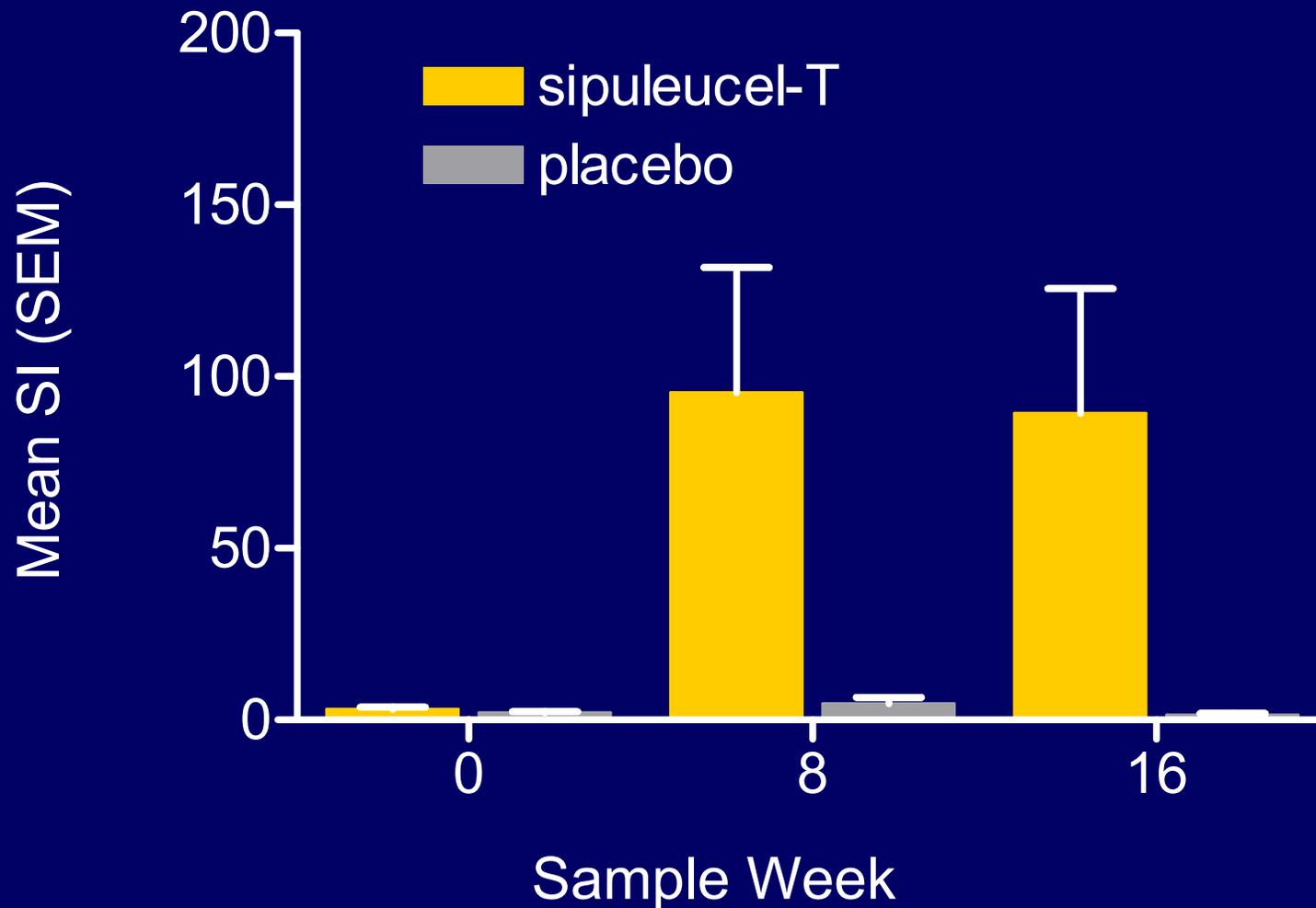
Secondary Endpoints Study 1

- Time to clinical progression
- Time to treatment failure
- Time to disease-related pain



- Objective radiographic responses (none)

T Cell Response to Immunizing Antigen Study 1 at Weeks 0, 8, and 16

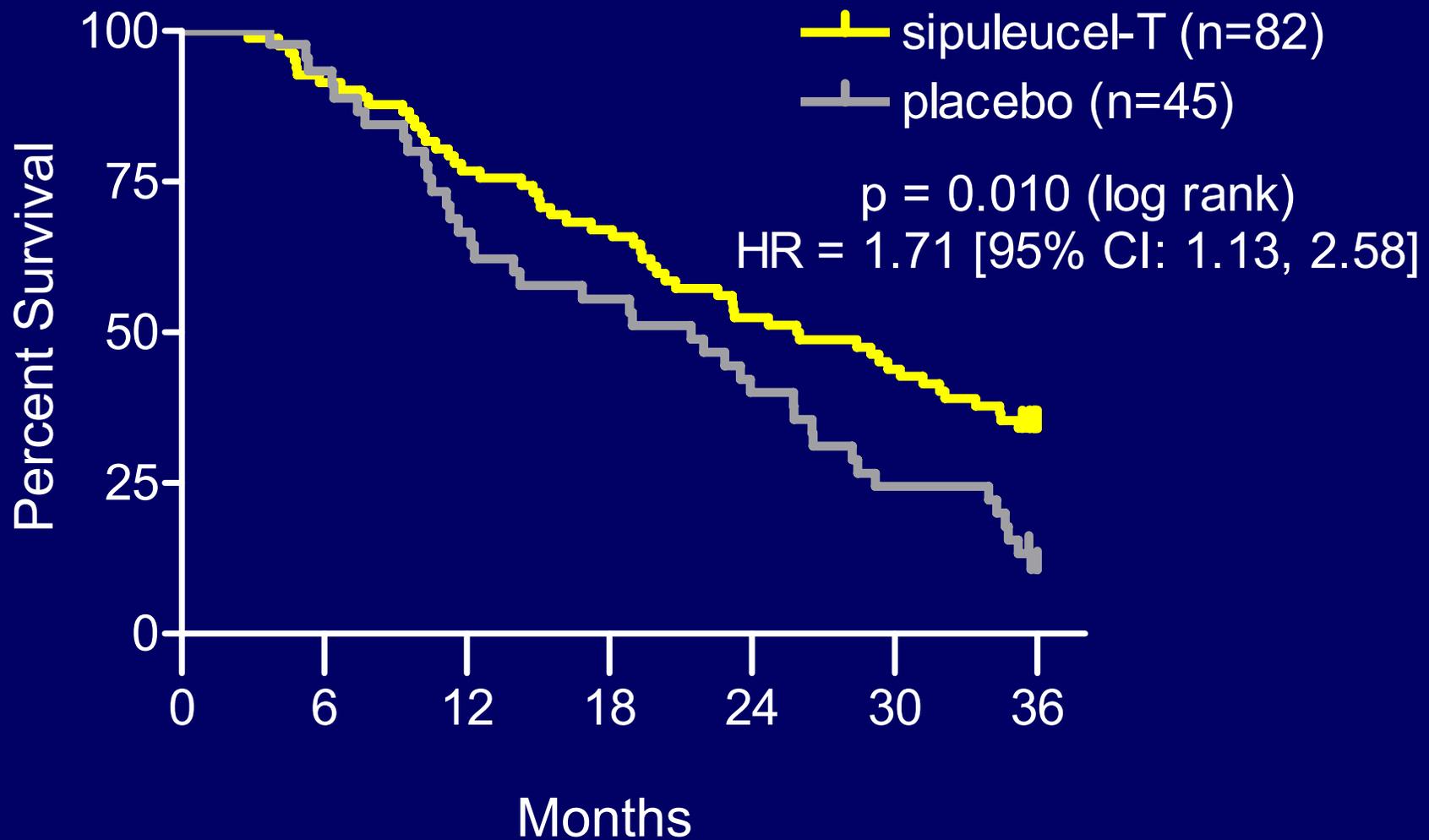


SI = stimulation index; SEM = standard error of the mean

Study 1

Overall Survival

Overall Survival Study 1



Overall Survival Summary

Study 1

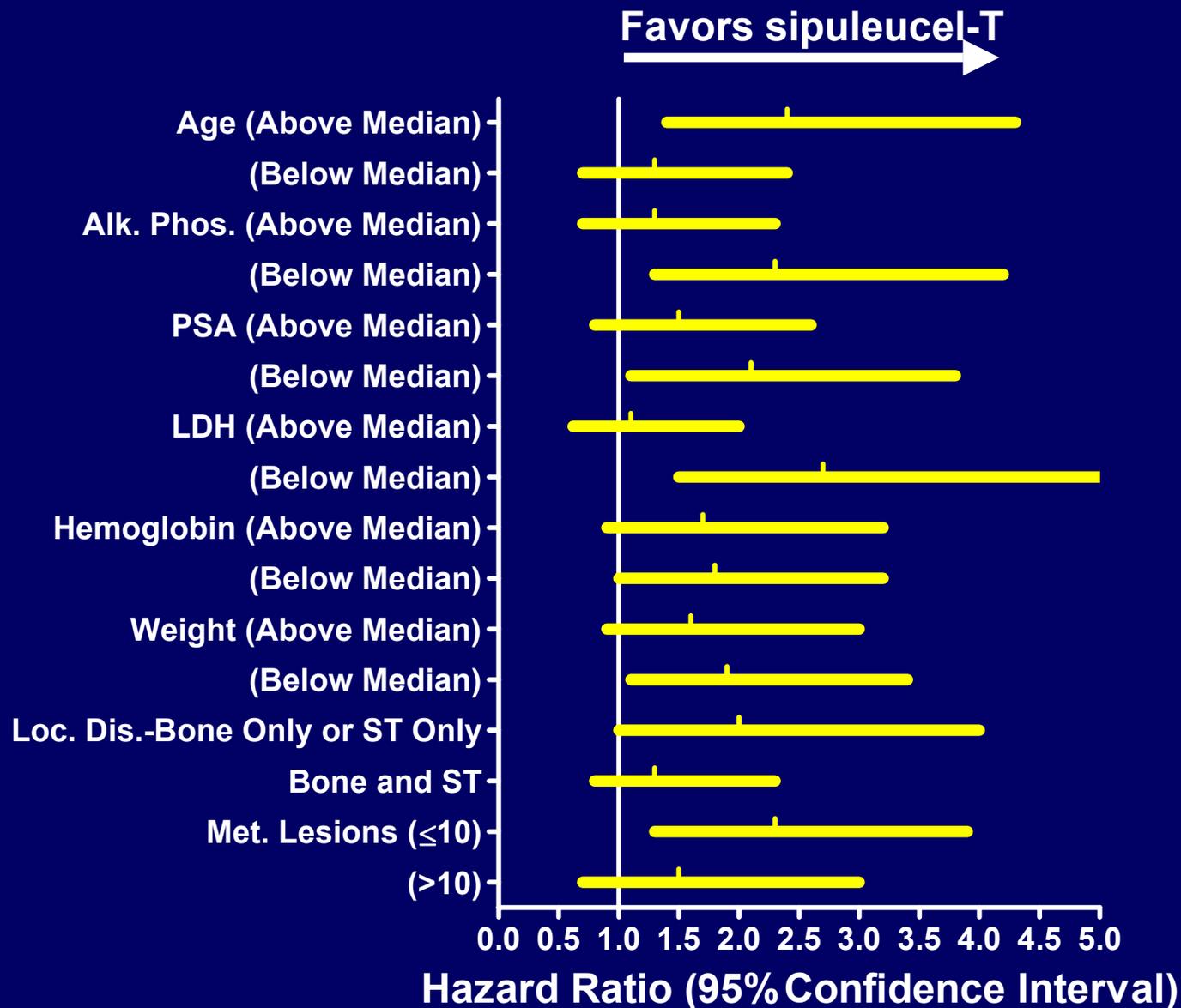
	N	Survival Percentiles (months)		
		75%	50%	25%
sipuleucel-T	82	14.3	25.9	≥ 36.0
placebo	45	10.5	21.4	30.9

	Survival Rates (percent)		
	12 months	24 months	36 months
sipuleucel-T	77	52	34
placebo	67	40	11

Sensitivity Analyses to Test Survival Result Robustness, Study 1

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

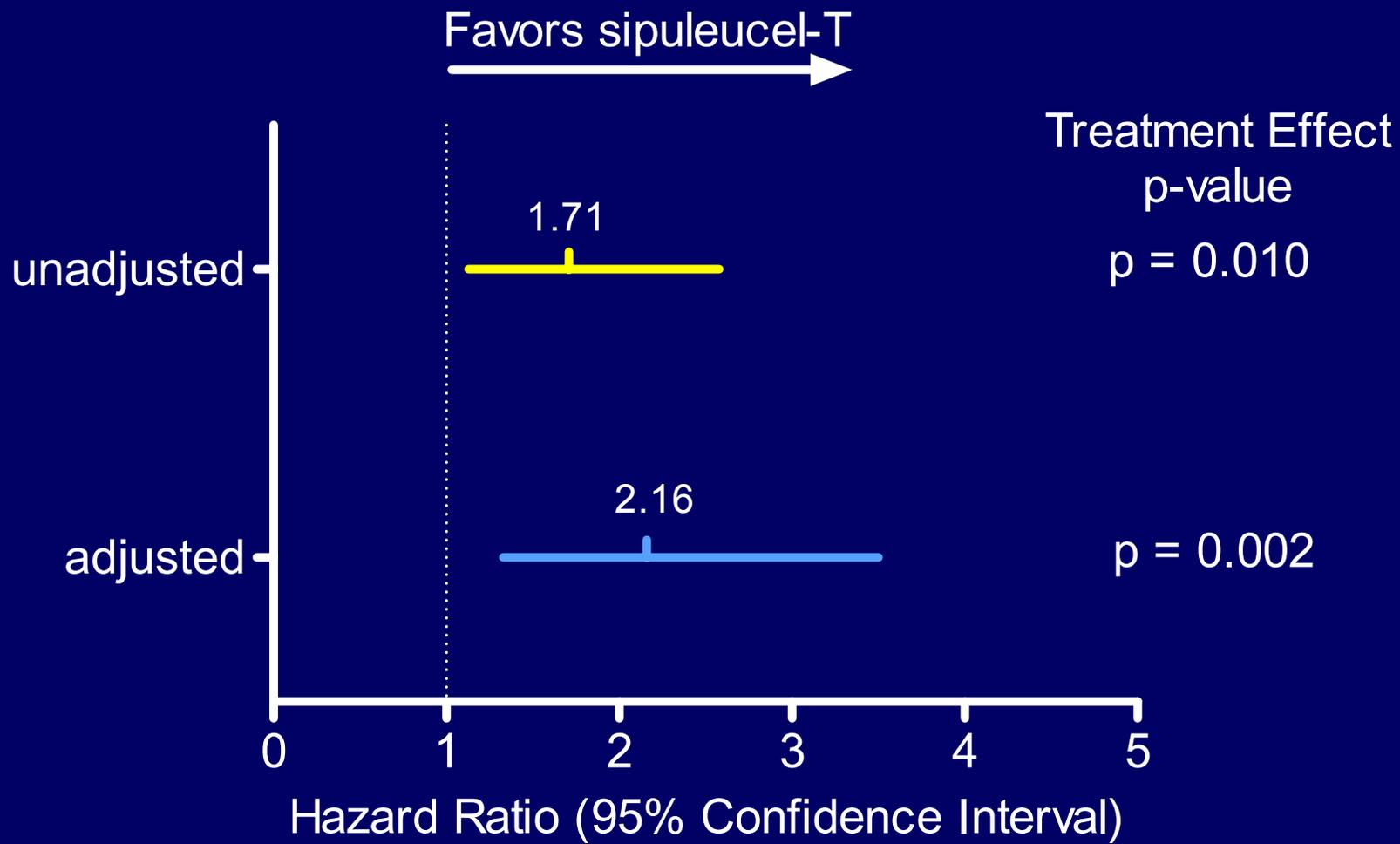
Treatment Effect Consistent Across Subpopulations, Study 1



Adjustment for Multiple Prognostic Factors Study 1

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

Survival Benefit Confirmed by Adjustment for Multiple Prognostic Factors, Study 1



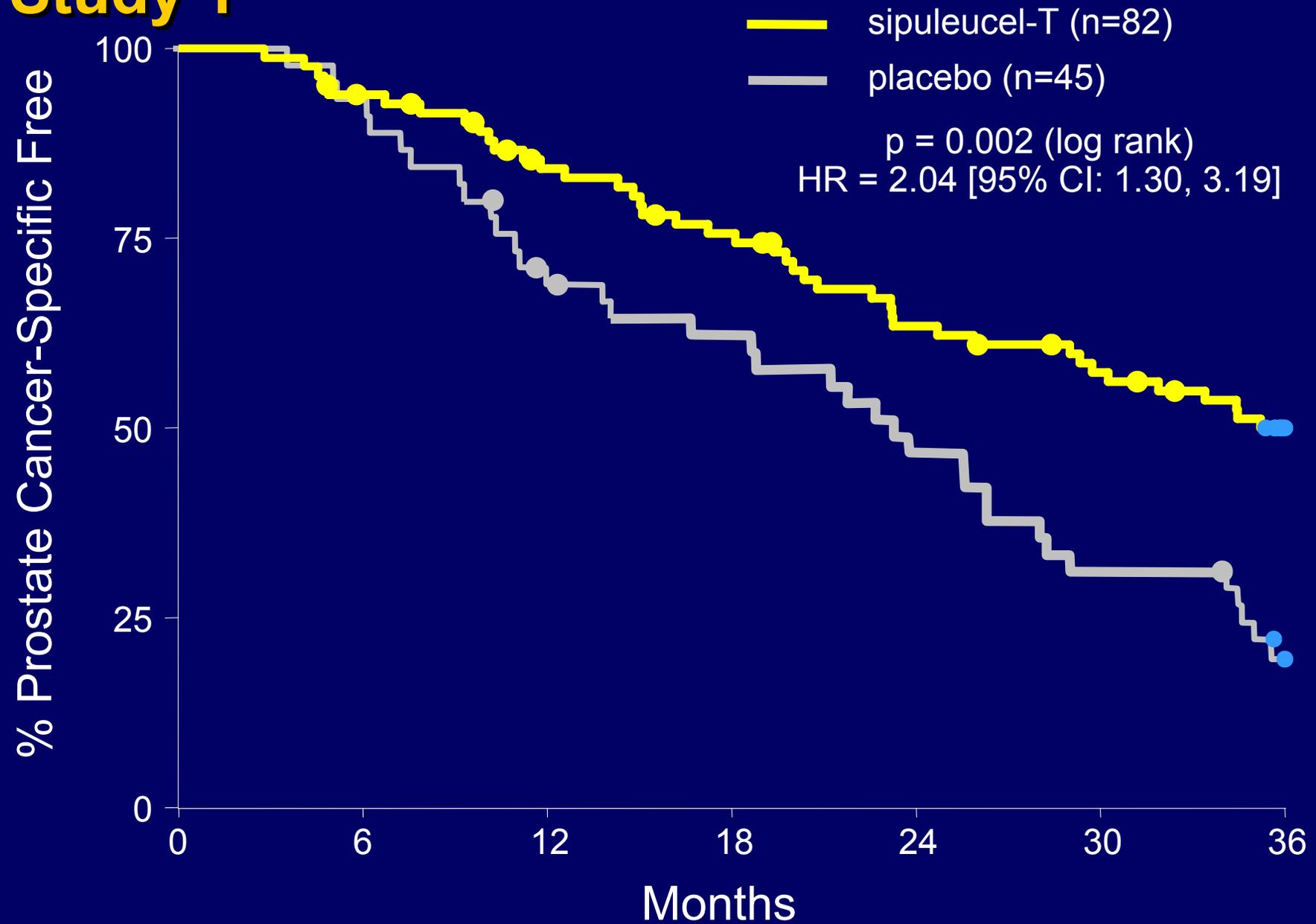
Chemotherapy Use Following Study Treatment Does Not Explain Survival Benefit

- No evidence of a difference in docetaxel use

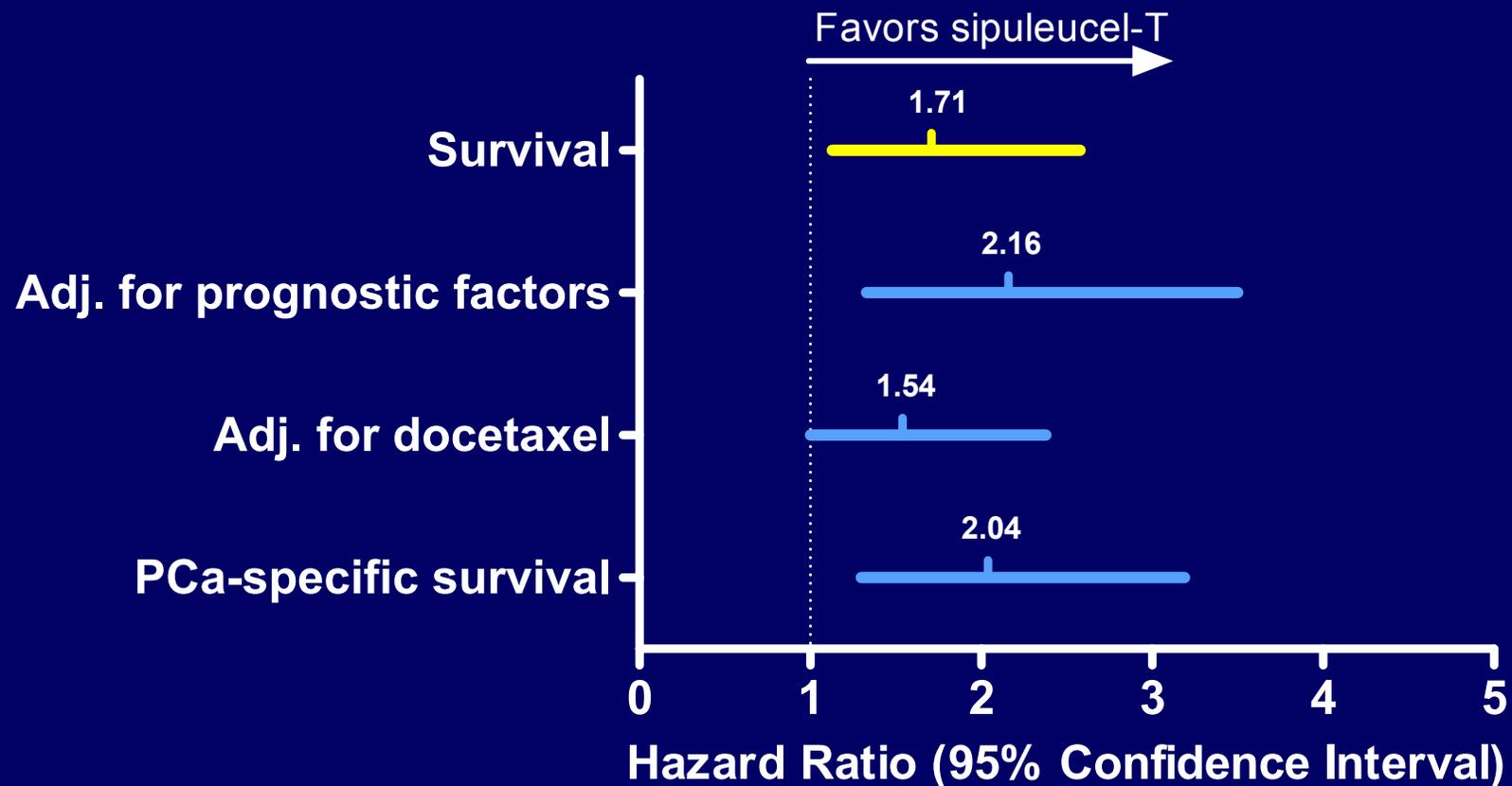
	<u>sipuleucel-T</u>	<u>placebo</u>
– Chemotherapy	56%	63%
– Docetaxel	37%	49%

- 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

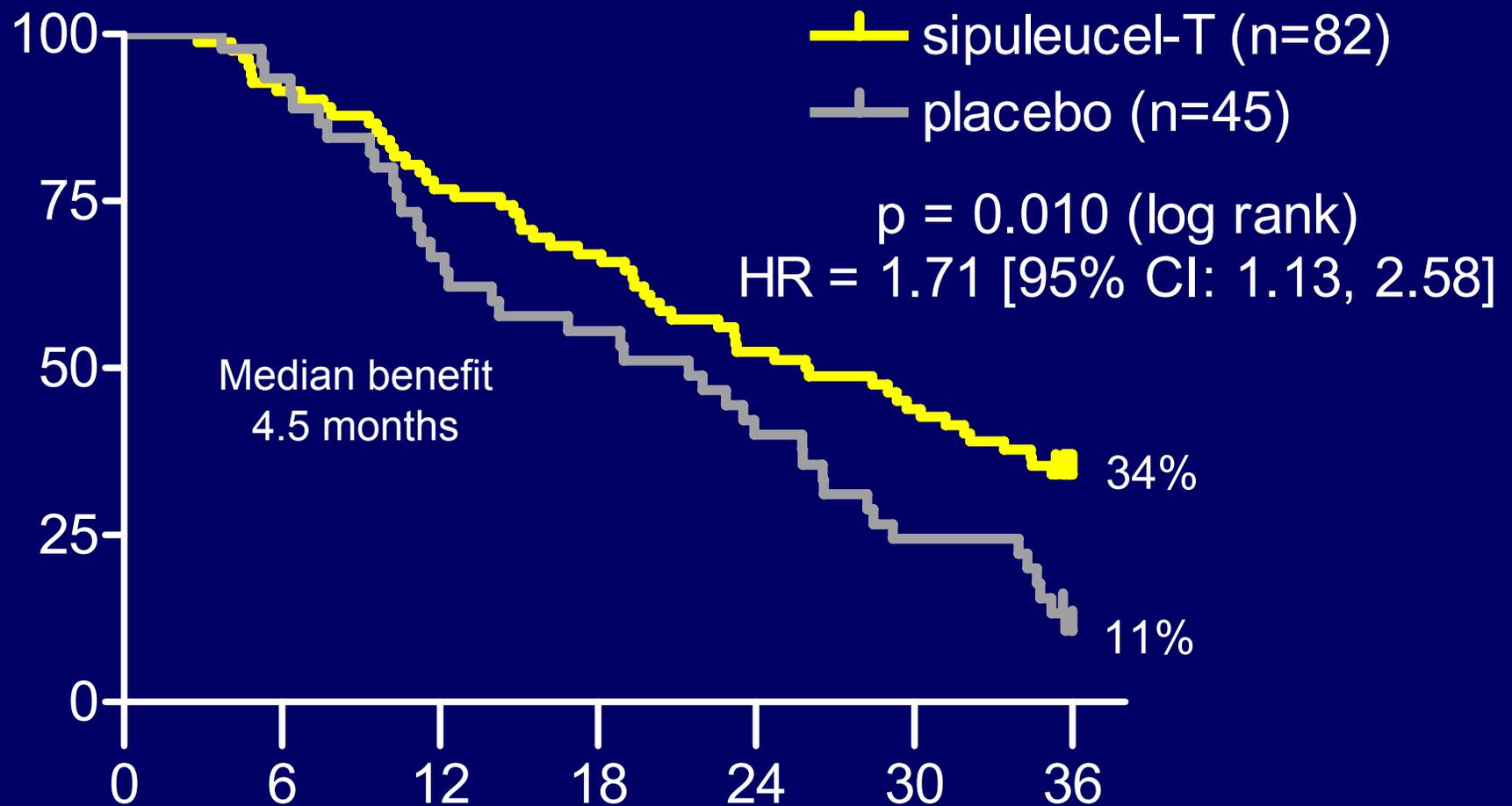
Prostate Cancer-Specific Survival Study 1



Survival Results Confirmed by Multiple Sensitivity Analyses, Study 1



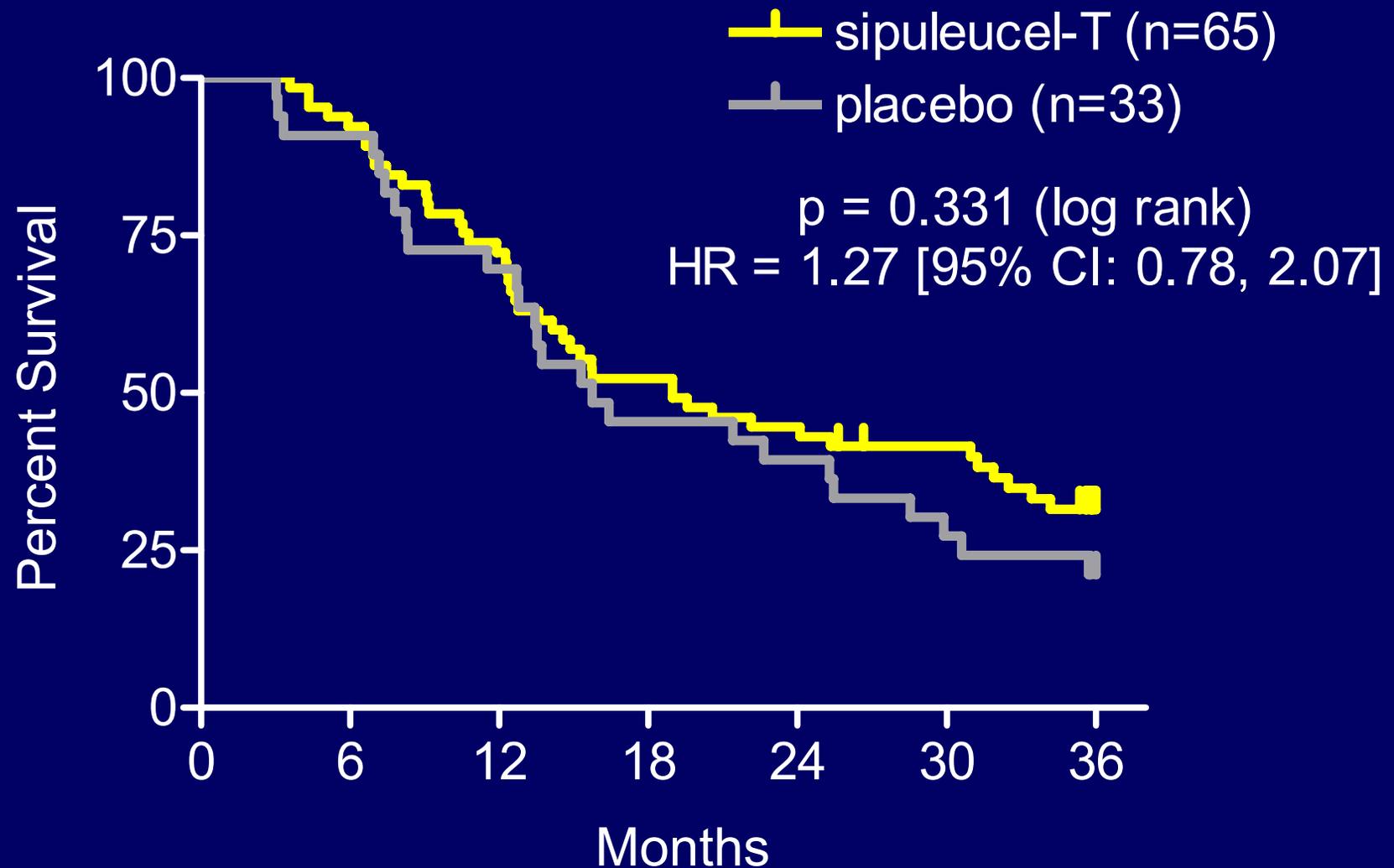
Clinically Significant and Statistically Persuasive Overall Survival Benefit



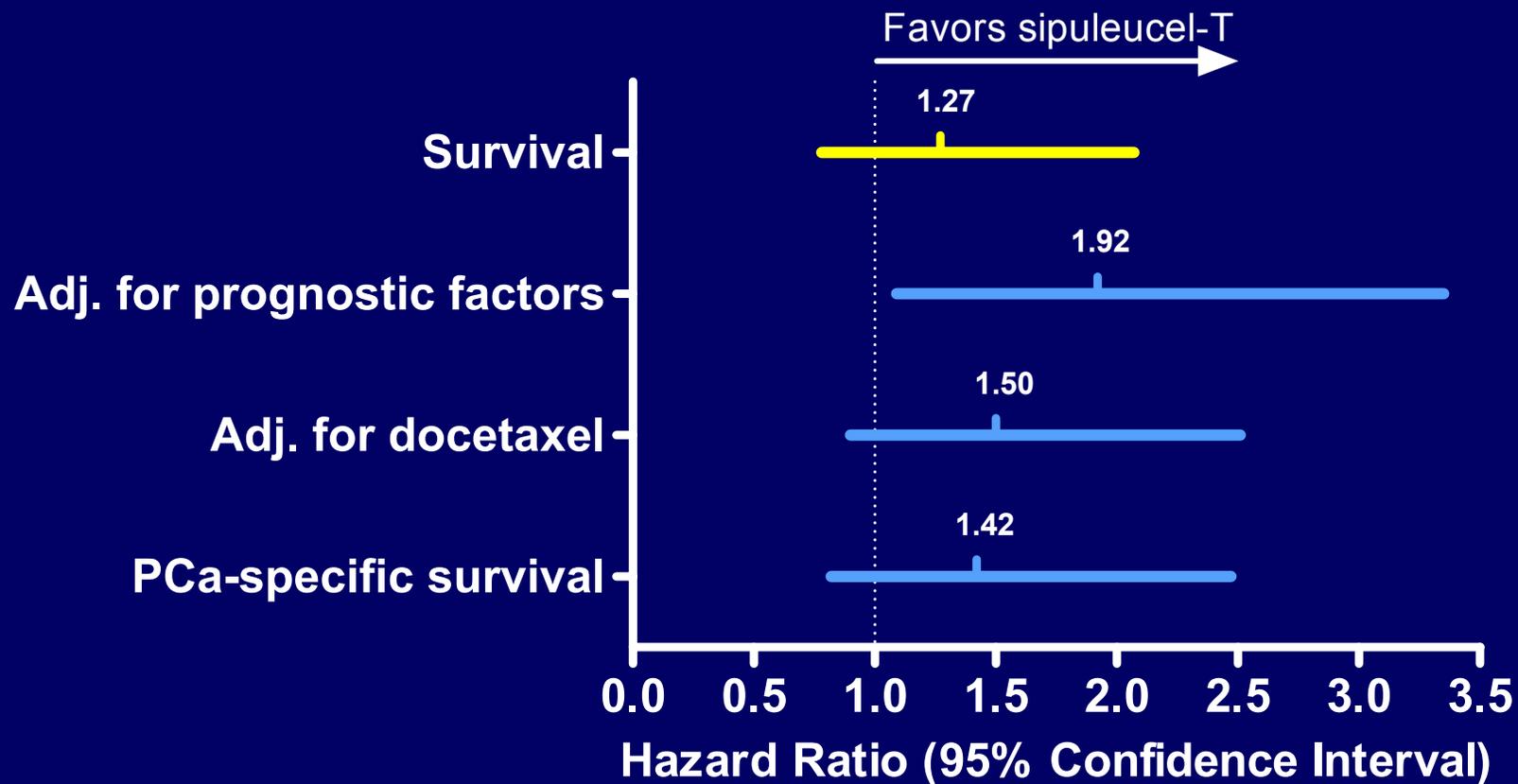
Study 2

Overall Survival

Overall Survival Study 2



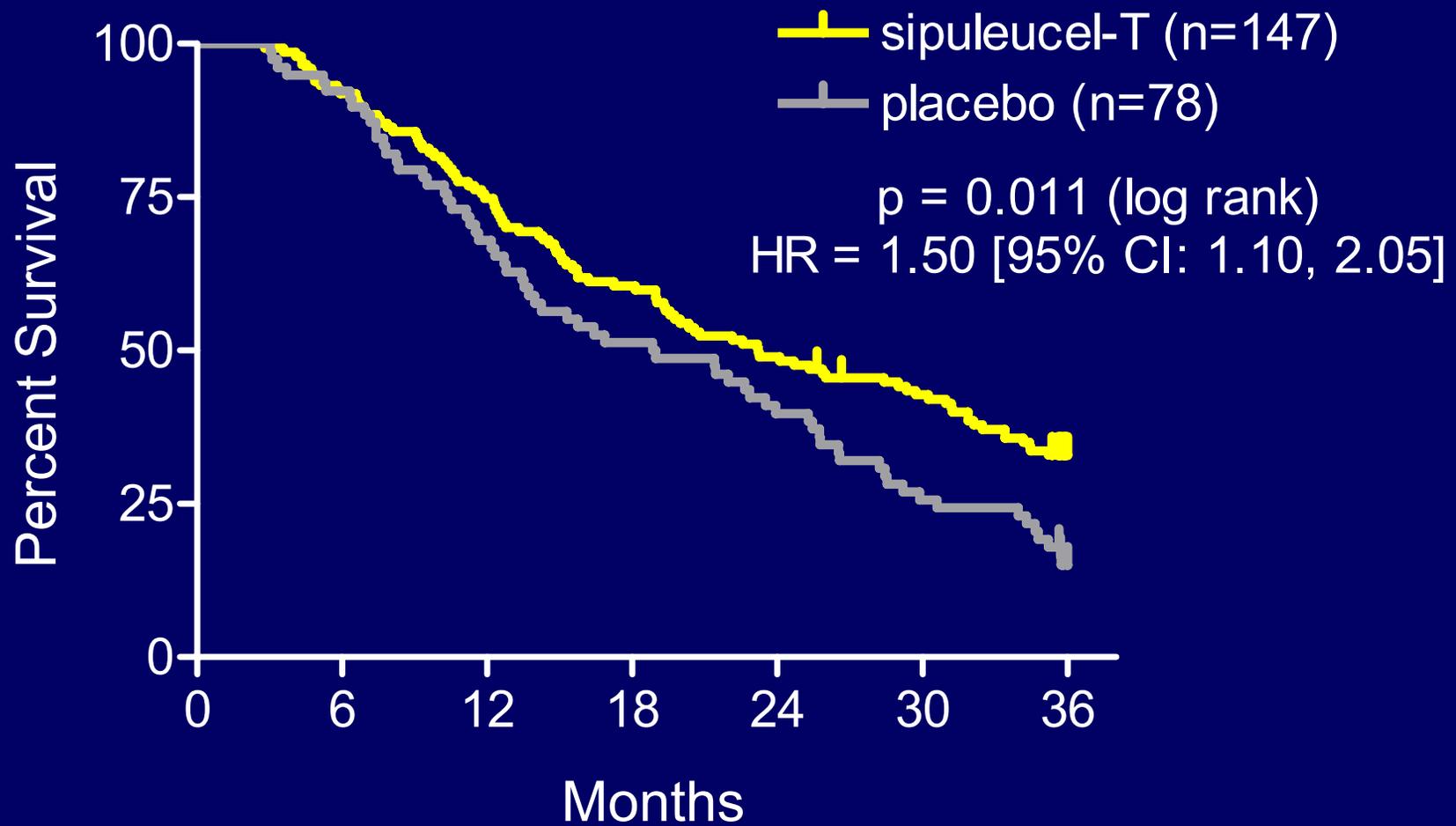
Sensitivity Analyses of Survival Results Study 2



Integrated Studies 1 & 2

Overall Survival

Overall Survival Integrated Studies 1 & 2



Clinical Efficacy Summary & Conclusions

Summary of Survival Benefit

	Primary	Supportive	
	Study 1 (N = 127)	Study 2 (N = 98)	Studies 1 & 2 Integrated (N = 225)
Hazard Ratio	1.71	1.27	1.50
p-value (log rank)	p = 0.010	p = 0.331	p = 0.011
Med. Survival Benefit: mos	4.5	3.3	4.3
36-Month Survival (%)			
sipuleucel-T	34%	32%	33%
placebo	11%	21%	15%

Study 1 Survival Benefit Unlikely to be False Positive: Primary Evidence

- Survival endpoint least variable and susceptible to bias
- Magnitude of the treatment benefit (HR = 1.71)
- Low nominal p-value ($p = 0.010$)
- Sensitivity analyses
 - Consistency of treatment effect in subpopulations
 - Adjustment for baseline prognostic factors
 - Adjustment for chemotherapy use
 - Prostate cancer-specific survival
- Additional Support
 - Time to disease progression & secondary endpoints (Study 1)
 - Overall survival (Study 2 and Integrated Studies 1 & 2)
 - Correlation between product potency and overall survival

Clinical Safety

Safety Population

10 Clinical Trials with Sipuleucel-T

Product	Patients	Infusions
All Cell Products	669	2181
sipuleucel-T*	478	1387
placebo (including salvage)*	191	794

*Numbers are estimates due to blinded data and include APC8026, a product similar to sipuleucel-T

Most Common Adverse Events ($\geq 5\%$) Higher Rate in Sipuleucel-T ($p \leq 0.05$), Integrated Studies 1 & 2

Preferred Term	sipuleucel-T N = 147 %	placebo N = 76 %
Chills	57.8	7.9
Pyrexia	32.0	6.6
Headache	19.0	6.6
Asthenia	14.3	3.9
Dyspnea	10.9	2.6
Vomiting	10.9	2.6
Tremor	8.8	0.0

Adverse Drug Reactions: Severity of Events Integrated Studies 1 & 2

Events	sipuleucel-T N = 147		placebo N = 76	
	Grade 1 or 2 %	Grade 3 or 4 %	Grade 1 or 2 %	Grade 3 or 4 %
Chills	53.0	4.8	7.9	0.0
Pyrexia	29.9	2.0	6.6	0.0
Fatigue	41.5	1.4	28.9	0.0
Headache	17.7	1.4	6.6	0.0
Nausea	13.6	0.7	7.9	0.0
Asthenia	14.3	0.0	3.9	0.0
Dyspnea	7.5	3.4	1.3	1.3
Vomiting	10.2	0.7	2.6	0.0
Tremor	8.8	0.0	0.0	0.0

Severity of ADRs by Median TNC Count Sipuleucel-T, Integrated Studies 1 & 2

	< 10 x 10 ⁹ Cells N = 73		≥ 10 x 10 ⁹ Cells N = 73	
	< Grade 3 %	≥ Grade 3 %	< Grade 3 %	≥ Grade 3 %
Any AE	61.6	37.0	79.4	19.1
Chills	47.9	6.8	58.9	2.7
Fatigue	43.8	1.4	38.4	1.4
Pyrexia	32.9	1.4	27.4	2.7
Headache	12.3	2.7	23.3	0.0
Nausea	12.3	1.4	15.1	0.0
Asthenia	17.8	0.0	11.0	0.0
Dyspnea	4.1	2.7	9.6	2.7
Vomiting	9.6	1.4	11.0	0.0
Tremor	5.5	0.0	12.3	0.0

Incidences of Serious Adverse Events* Integrated Studies 1 & 2

SAE Preferred Term	sipuleucel-T N = 147 n (%)	placebo N = 76 n (%)
Any SAE	35 (23.8)	17 (22.4)
Chills	5 (3.4)	0 (0.0)
Dehydration	3 (2.0)	2 (2.6)
Dyspnea	4 (2.7)	1 (1.3)
Urinary retention	2 (1.4)	3 (3.9)
Hematuria	2 (1.4)	2 (2.6)
Pyrexia	4 (2.7)	0 (0.0)
Cerebrovascular accident	3 (2.0)	0 (0.0)
Deep vein thrombosis	0 (0.0)	2 (2.6)

*For SAEs occurring in $\geq 2\%$ of patients in either arm.

Incidence of Cerebrovascular Events All Randomized Studies (As Randomized)

Events	N*	sipuleucel-T	placebo	OR (95% CI)
All Studies	461/231	3.9%	2.6%	1.52 (0.60, 3.89)

*sipuleucel-T/placebo

Incidence of Cerebrovascular Events All Randomized Studies (As Randomized)

Events	sipuleucel-T N = 461	placebo N = 231	OR (95% CI)
All Events	3.9%	2.6%	1.52 (0.60, 3.89)
• Ischemic	2.4%	2.2%	1.10 (0.38, 3.22)
• Hemorrhagic	0.6%	0.4%	1.51 (0.16, 14.56)
• Unknown	0.9%	0.0%	NA
Deaths	1.5%	0.9%	1.77 (0.36, 8.57)

Cerebrovascular Events

Summary of Analyses

- **Additional Analyses**
 - Variable time to onset
 - No evidence of increased risk of non-neurologic vascular events
 - No correlation with cell dose or CD54 upregulation
 - Event rate consistent with advanced prostate cancer population (SEER-Medicare analysis)
- **Summary**
 - 1.3% increased incidence in sipuleucel-T vs placebo
 - Large p-values and wide confidence intervals associated with small numbers of events
 - Pharmacovigilance plan

Additional Safety Observations

- **No evidence of increased incidence of autoimmune events**
- **No evidence of increased incidence of secondary malignancies**
- **No deaths attributed to product, as reported by study Investigators**

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**

Agenda

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Elizabeth Smith

**Clinical Development,
Efficacy, and Safety**

Mark Frohlich, MD

**Development History and
Key Product Attributes**

Nicole Provost, PhD

Clinical Practice

Christopher Logothetis, MD

Benefits & Risks

Elizabeth Smith

Development History and Key Product Attributes

Nicole Provost, PhD

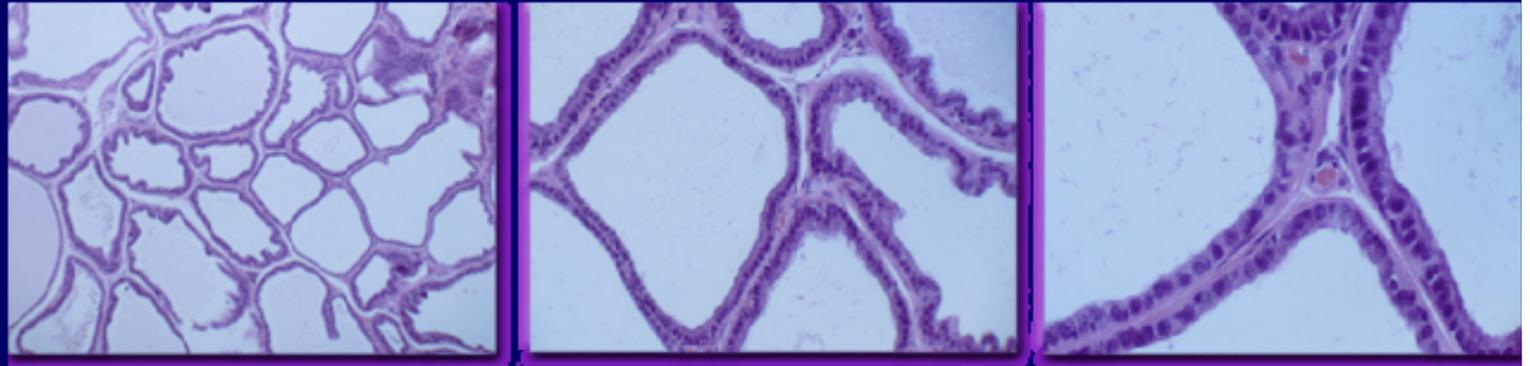
Vice President, Product Development

Pre-Clinical Rationale

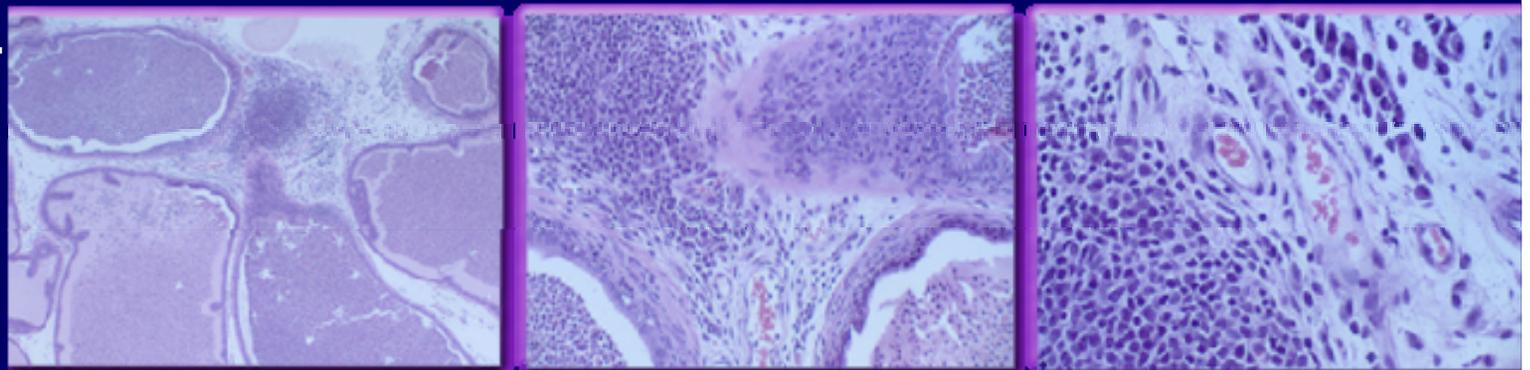
- **Antigen-loaded APCs isolated from peripheral blood showed clinical promise in lymphoma**
- **Prostatic acid phosphatase (PAP) highly expressed in prostate tissue**
- **Granulocyte Macrophage Colony Stimulating Factor (GM-CSF) activates APCs**
- **Rat APCs, loaded with PAP+GM-CSF fusion protein, induced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

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

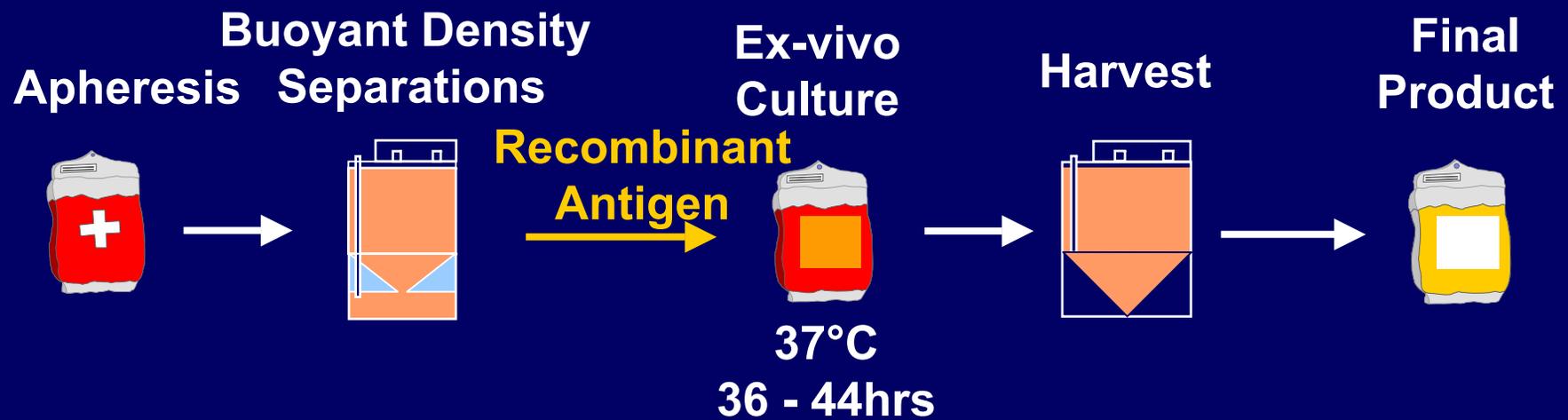
Control



rPAP-GMCSF
treated



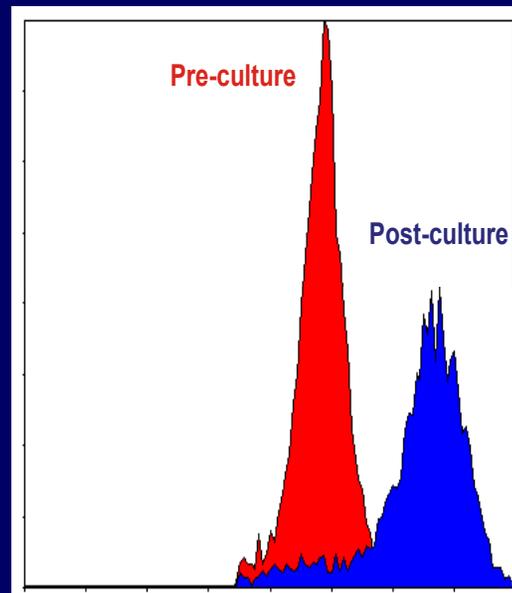
Sipuleucel-T Process Overview



Key Product Release Parameters

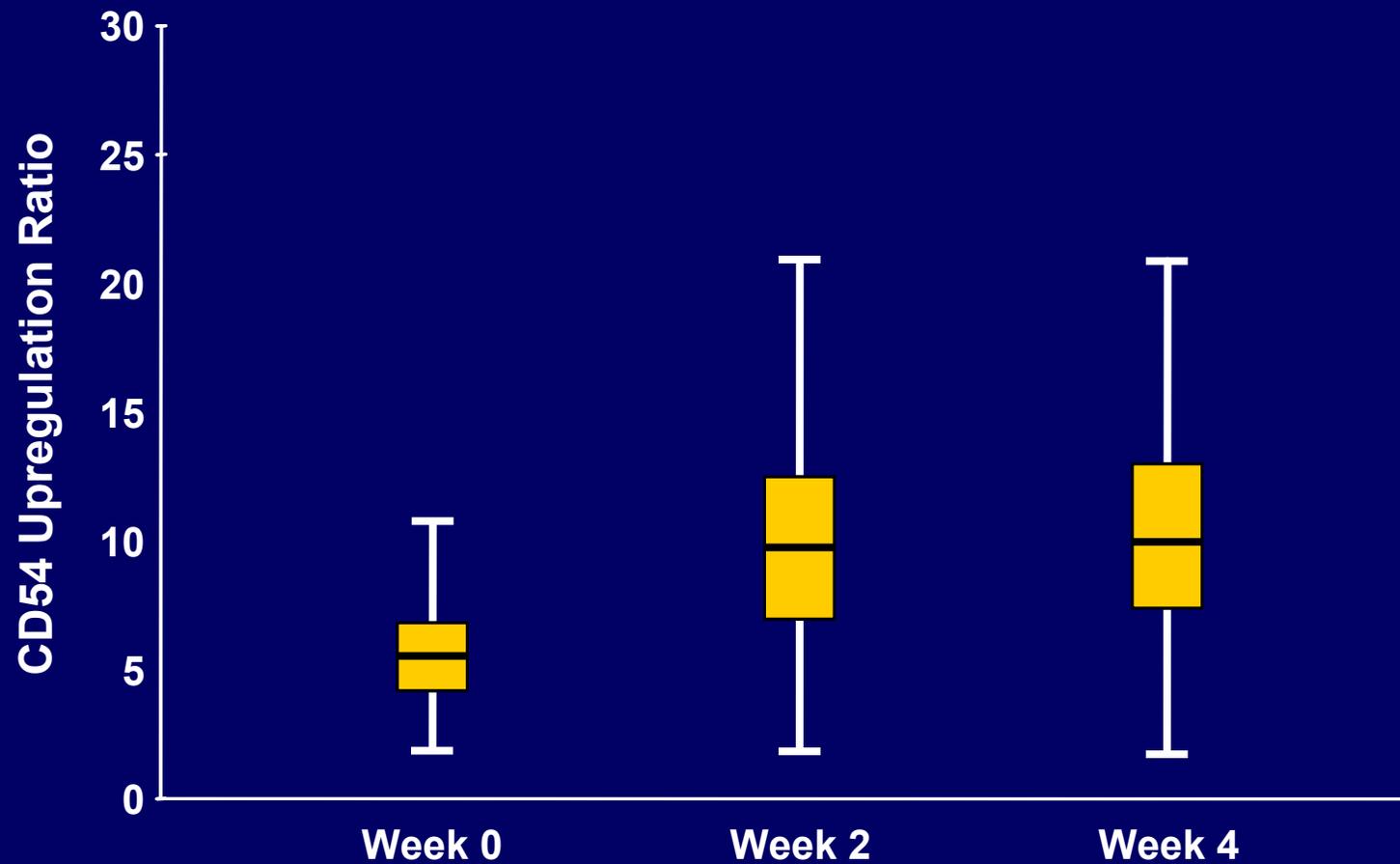
- **Potency**
 - CD54 upregulation on APCs
 - CD54⁺ APC count
- **Total Nucleated Cell (TNC) count**
- **Identity**
- **Viability**
- **Sterility and other safety tests**

CD54 Upregulation Potency Assay for APCs



Mean Fluorescence
Intensity

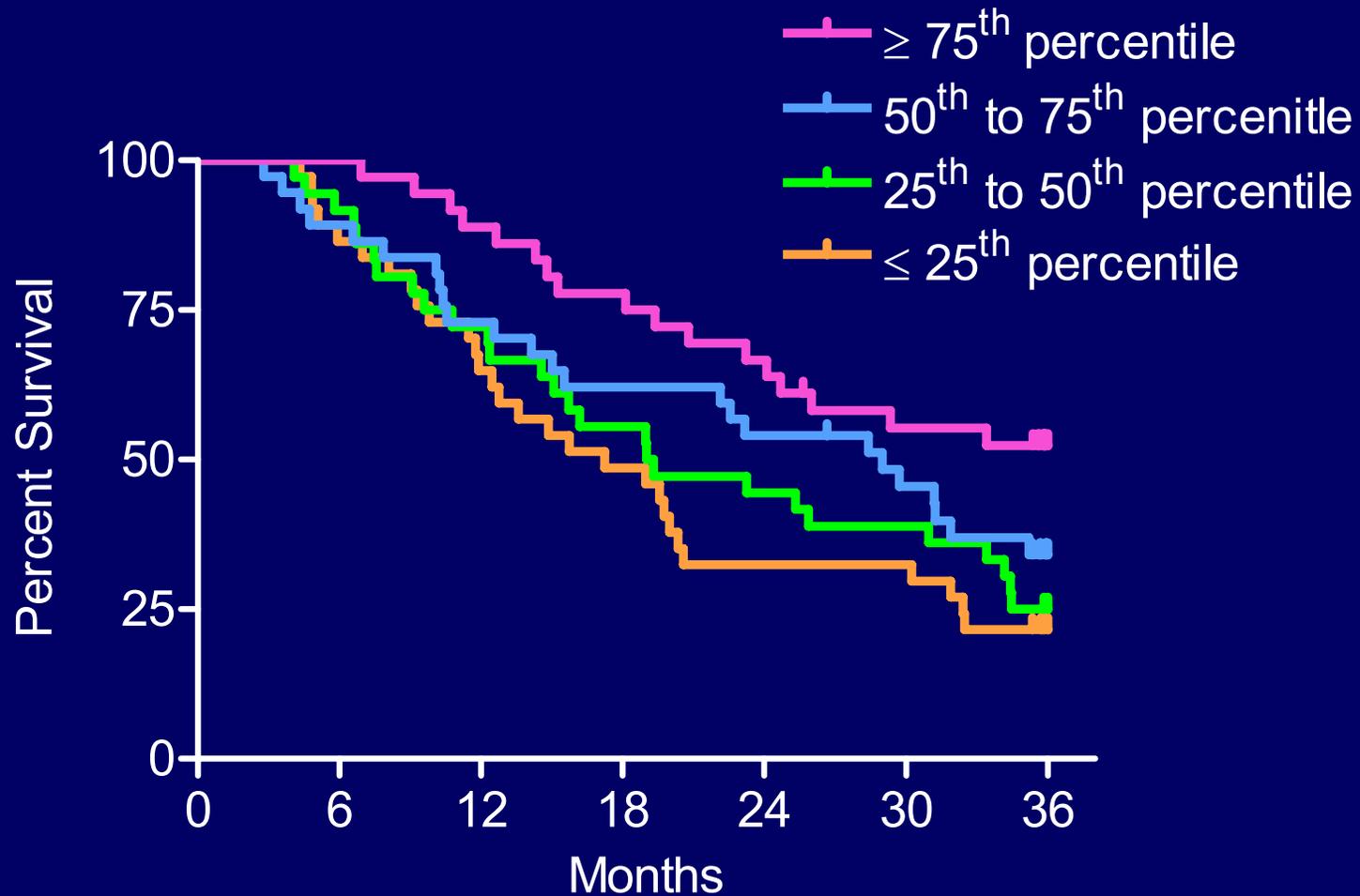
CD54 Upregulation by Treatment Week Phase 3 Manufacturing Data



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

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



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

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**
- **Support the efficacy findings**

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**Androgen Independent
Prostate Cancer (AIPC):
*Challenges and Current Clinical
Practice***

Christopher Logothetis, MD
Professor of Medicine
MD Anderson Cancer Center

Agenda

- **Challenges with clinical trial design in advanced prostate cancer**
- **Current clinical practice in advanced prostate cancer**

Limitations of Trial Endpoints in Advanced Prostate Cancer

Response

- Bone scan not sensitive or specific
- PSA controversial

Progression

- Inconsistent definitions
- Bone scan issues
- Inconsistent correlation with survival

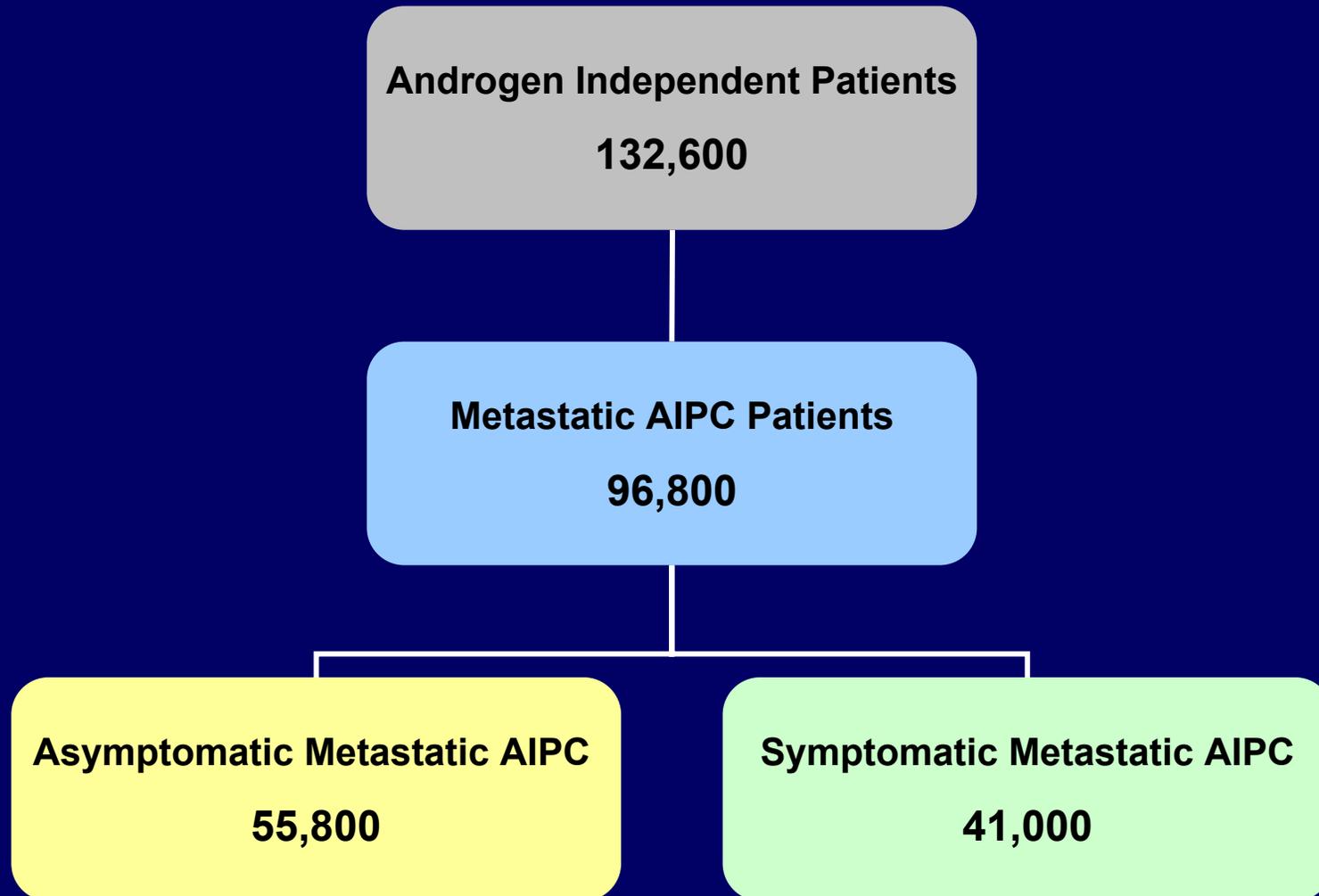
Survival

- Most reliable & clinically meaningful

Challenges of Trial Design in Active Cellular Immunotherapy

- Rapid rate of disease progression in AIPC
- Delayed onset of activity
- Distant endpoint (survival) provides more power to demonstrate treatment effect

Advanced Prostate Cancer



Treatment Options Patients with Early Prostate Cancer

Hormone Sensitive

Disease State:	Localized Disease	Initial Serologic Recurrence
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Treatment Options:	Surveillance Surgery Radiation	Surveillance Hormone Therapy
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Expected Survival:	> 15 years	> 10 years
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Treatment Options

Patients with Advanced Prostate Cancer

Hormone Resistant

Disease State:

2° Serologic
Recurrence

Metastatic

Asymptomatic

Symptomatic

Treatment Options:

Surveillance

Surveillance

Palliative Care

2° Hormones

2° Hormones

Chemotherapy

Chemotherapy

Expected Survival:

≤ 5 years

14-22 months

< 18 months

Currently Approved Agents for Advanced Prostate Cancer

Treatment

Basis for Approval

Zoledronate (Zometa®)

Skeletal related events

Estramustine phosphate

Endocrine effects

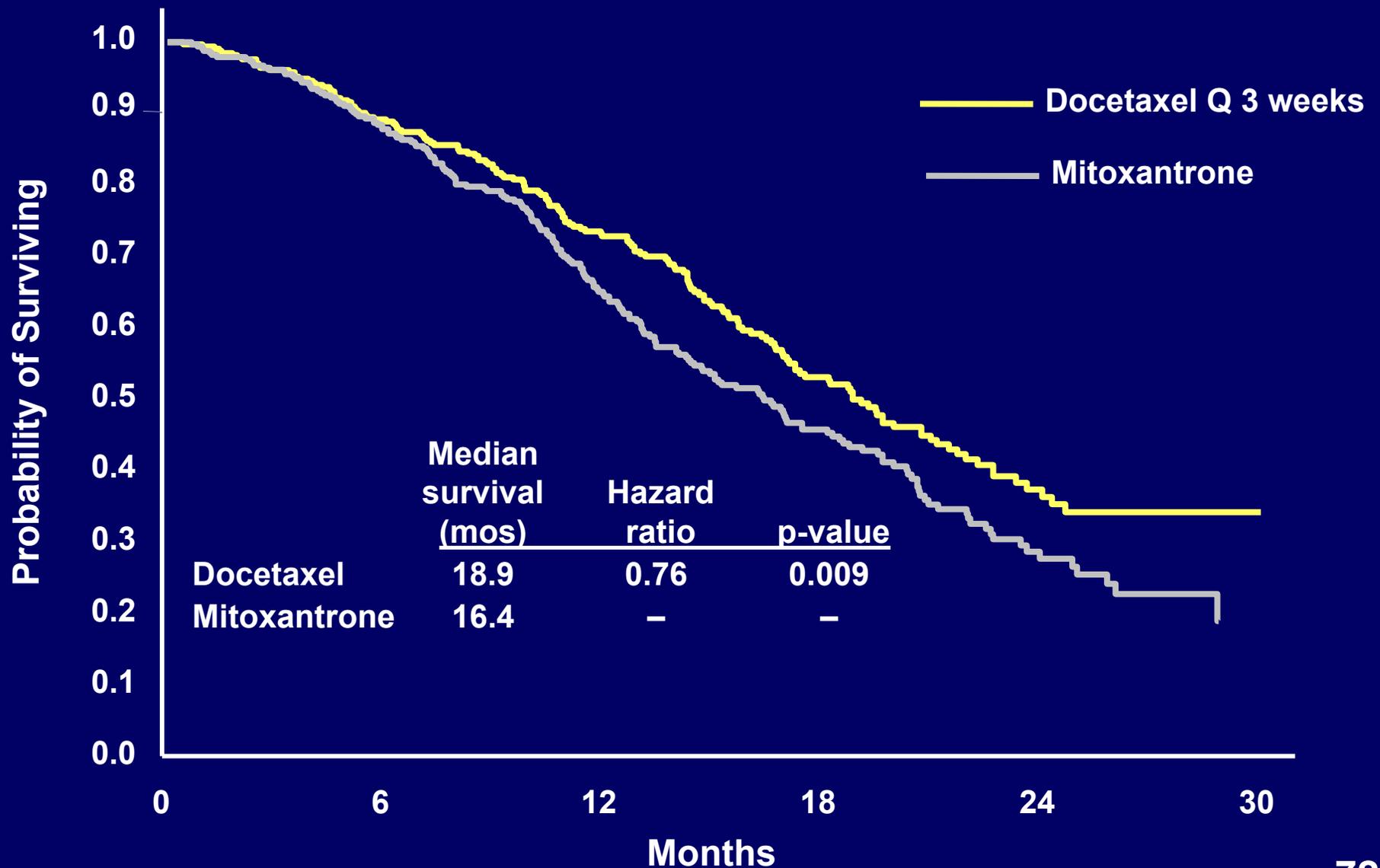
Mitoxantrone (Novantrone®)

Palliative response

Docetaxel (Taxotere®)

Overall survival

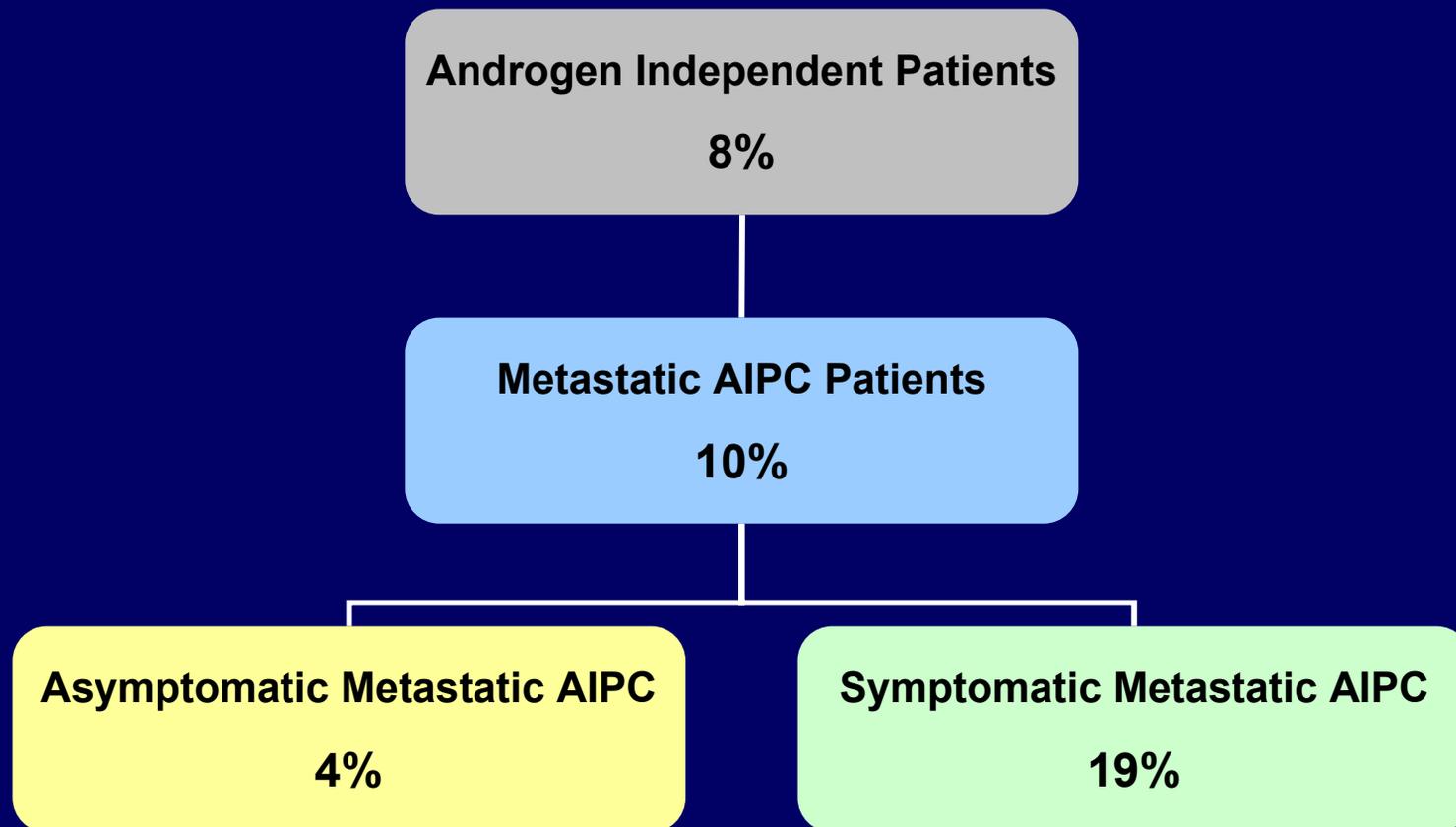
Docetaxel Impact on Overall Survival



Relationship of Symptom State to Benefit from Docetaxel (TAX 327)

	Docetaxel Q 3 wks median survival (months)	Mitoxantrone median survival (months)	Δ (months)	Hazard Ratio
Asymptomatic (N = 367)	23.0	19.8	3.2	0.73 (p = 0.009)
Symptomatic (N = 305)	14.9	12.8	2.1	0.85 (p = 0.17)

Limited Acceptance of Docetaxel as Reflected in Current Usage



Role of Sipuleucel-T Advanced Prostate Cancer

Hormone Resistant

Disease State:

2° Serologic
Recurrence

Metastatic

Asymptomatic

Symptomatic

Treatment Options:

Surveillance

Surveillance

Palliative Care

2° Hormones

2° Hormones

Chemotherapy

Chemotherapy

Expected Survival:

≤ 5 years

< 2 years

< 18 months

— sipuleucel-T —

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Benefits & Risks

Elizabeth Smith

Risk/Benefit

Elizabeth Smith

Vice President, Regulatory Affairs

Known Risks of Sipuleucel-T

- **Known risks**
 - Chills, fatigue/asthenia, fever, headache, nausea, vomiting, dyspnea and tremor
- **Management**
 - Acetaminophen and diphenhydramine

Potential Risks of Sipuleucel-T

- **Complications related to central venous access**
- **Requirement for re-leukapheresis**
- **Possible increased risk of cerebrovascular events**

Benefits of Sipuleucel-T

- **Clinically significant prolongation of overall survival**
- **Short treatment duration**
- **High compliance rate**
- **Favorable safety profile**
- **Does not preclude other therapies**

PROVENGE[®] **(sipuleucel-T)**

Experts Available for Questions & Answers

- **Investigators**
 - **Eric Small, MD**
 - **Professor in Residence, Medicine and Urology, Member and Co-Leader, Prostate Cancer Program, UCSF Comprehensive Cancer Center**
 - **Celestia Higano, MD**
 - **Associate Professor, Departments of Medicine and Urology, School of Medicine, University of Washington**
 - **Paul Schellhammer, MD**
 - **Program Director, Virginia Prostate Center; Professor of Urology, Eastern Virginia Medical School**

Experts Available for Questions & Answers

- **Medical Oncologist**
 - **Christopher Logothetis, MD**
 - **Professor and Chair, GU Medical Oncology, Center Director GU Program, MD Anderson Cancer Center**
- **Immunologist**
 - **Hyam Levitsky, MD**
 - **Professor of Oncology, Medicine, Urology, Johns Hopkins University**
- **Statistician**
 - **Brent Blumenstein, PhD**
 - **Principal Consultant, Trial Architecture Consulting Fellow, American Statistical Assoc.**

Q&A Slides Presented

Overall Survival: Study 1 & Study 2

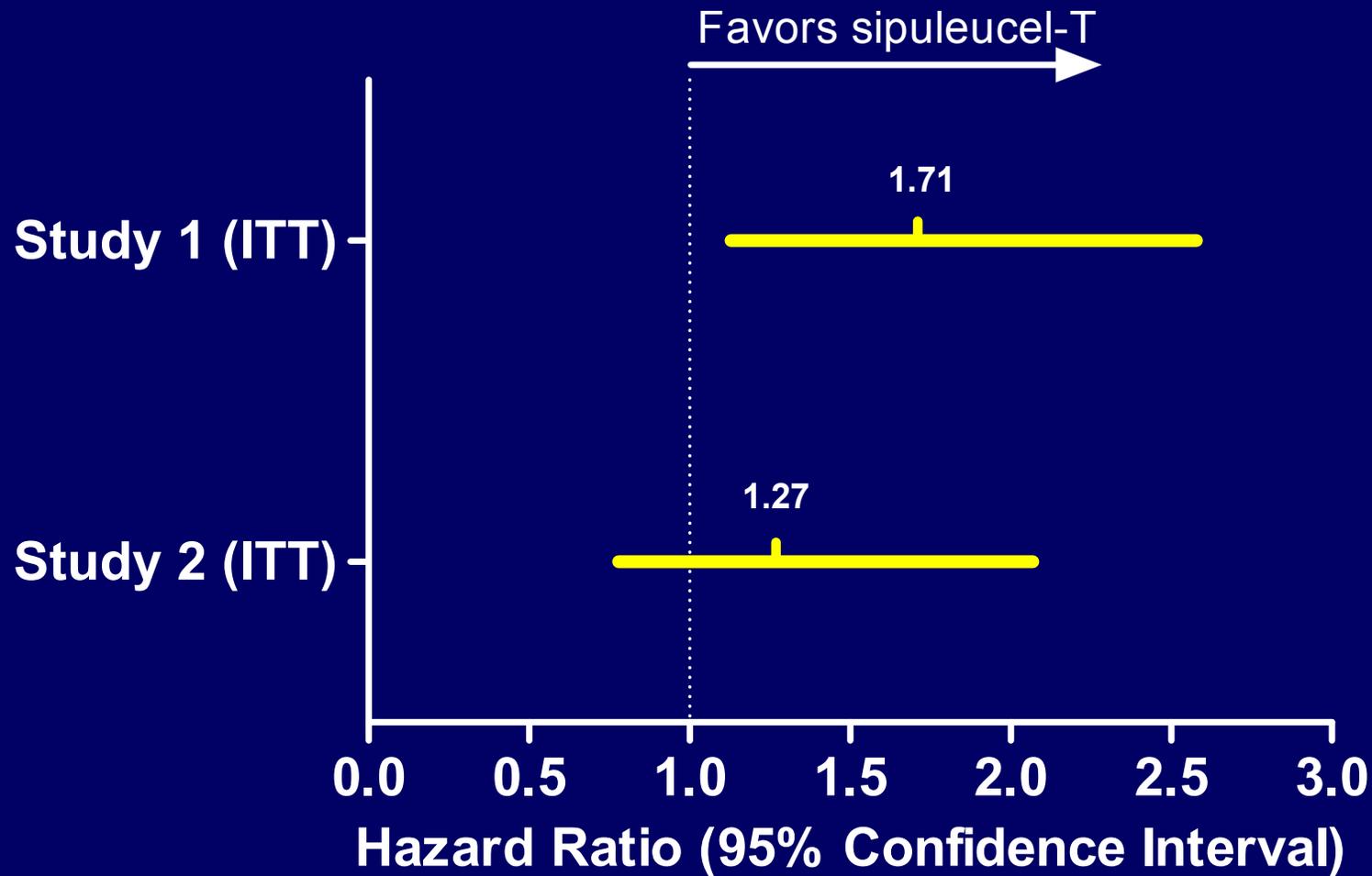


Figure 36. Composition of the CD54+ Cell Population in Sipuleucel-T over Successive Treatments

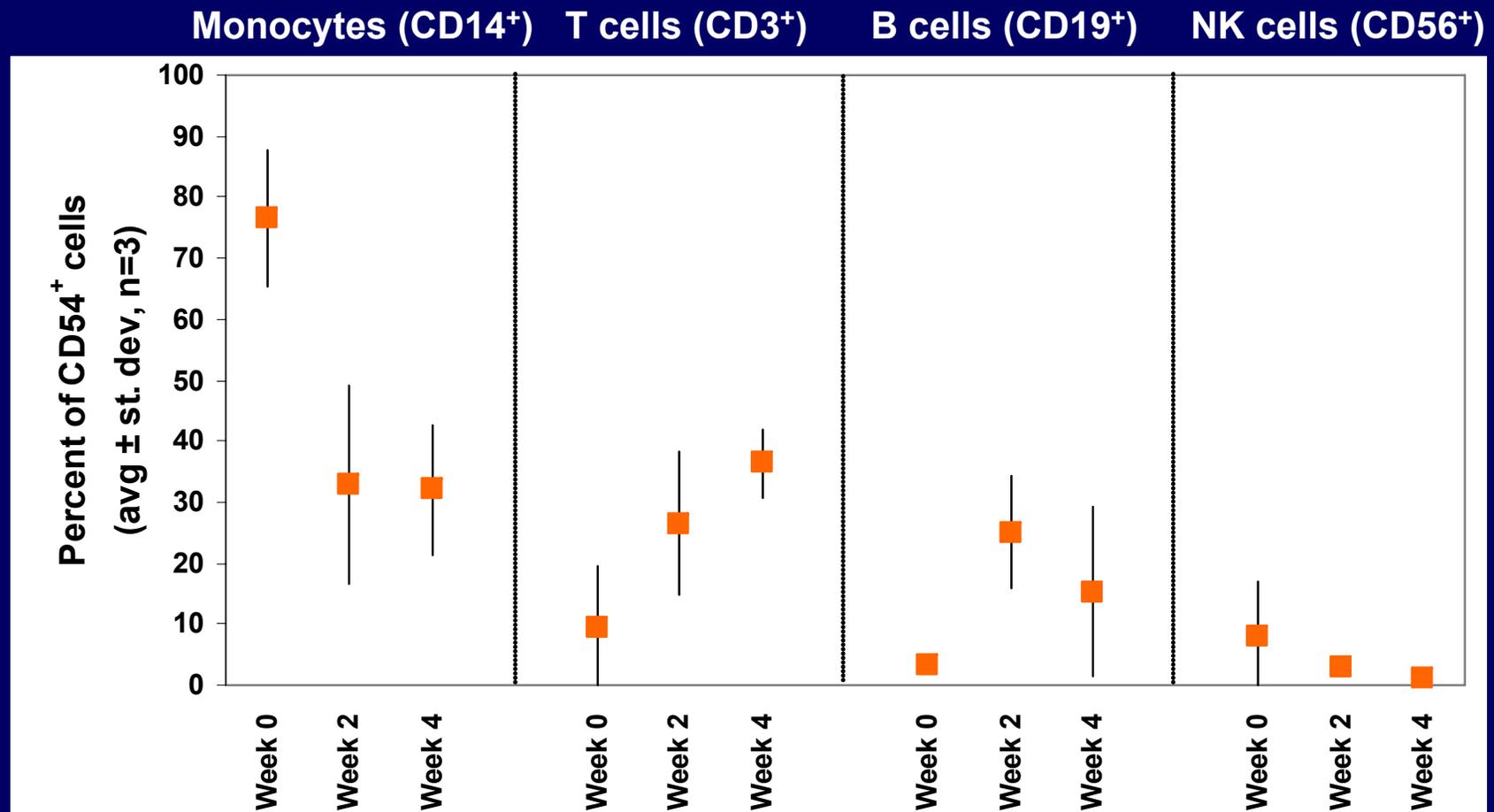
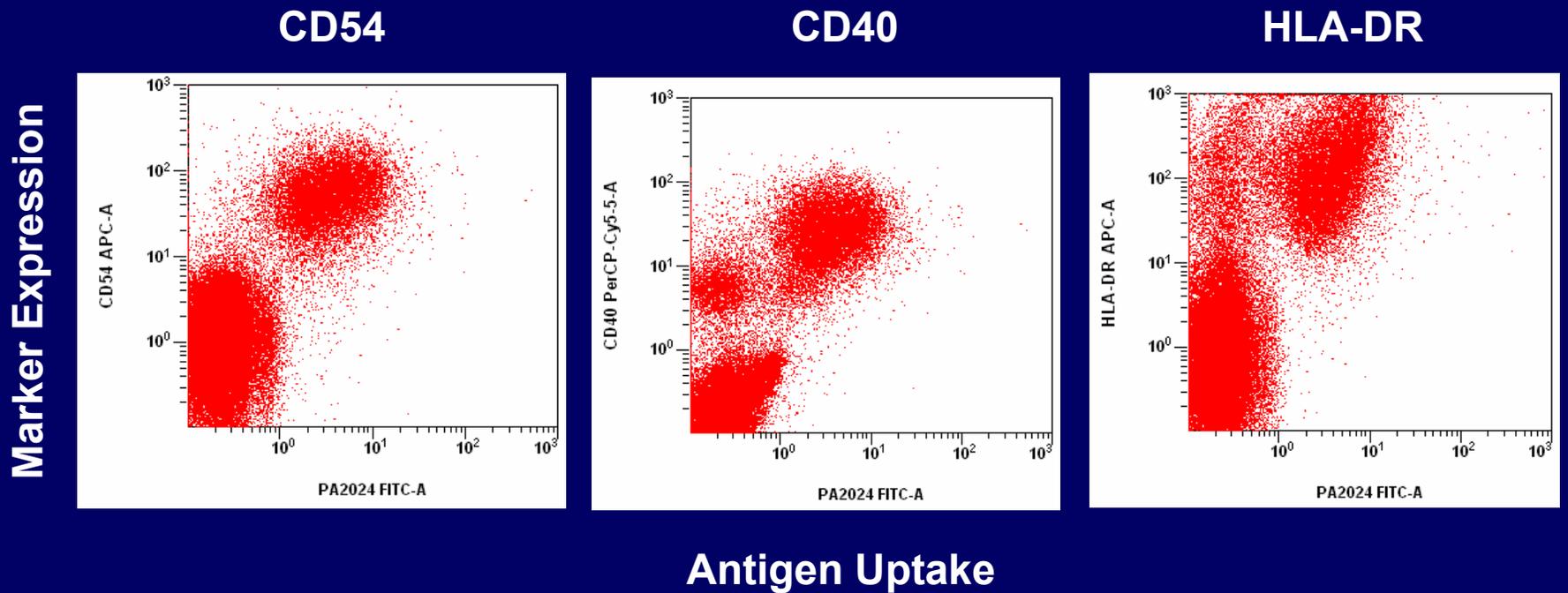


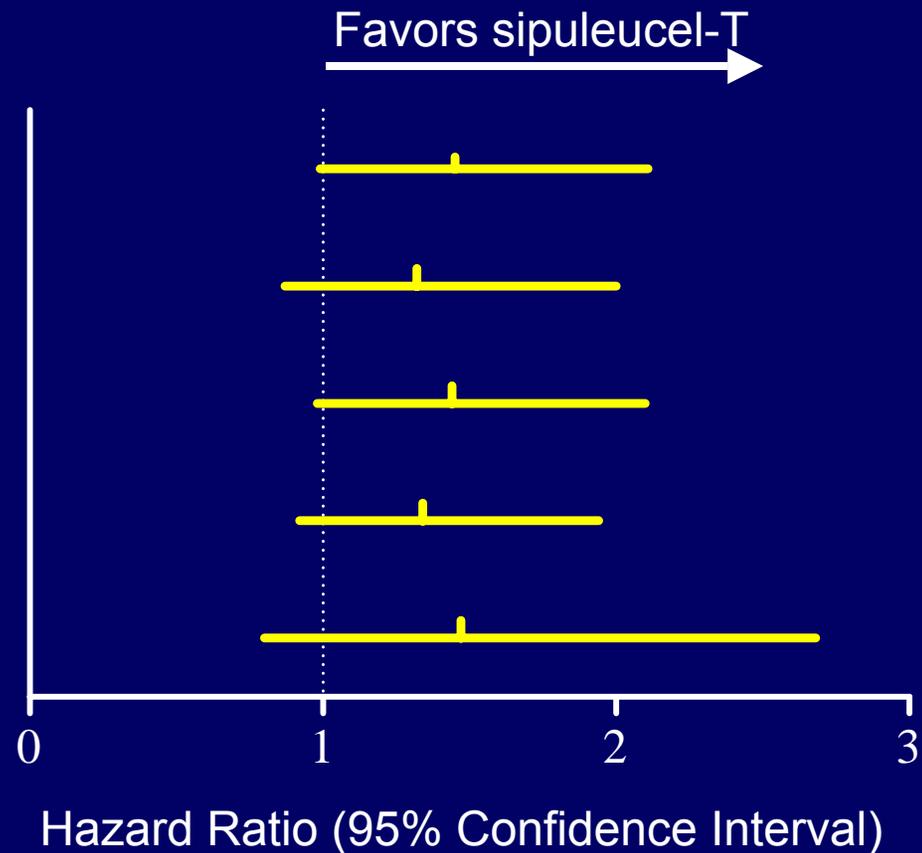
Figure 10. Antigen Uptake and Expression of Immune Synapse Proteins



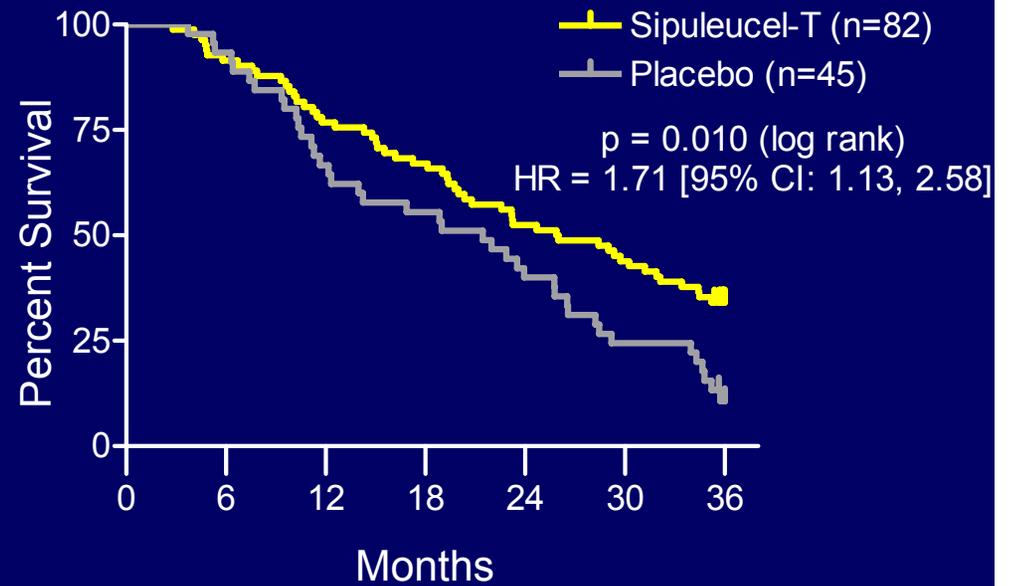
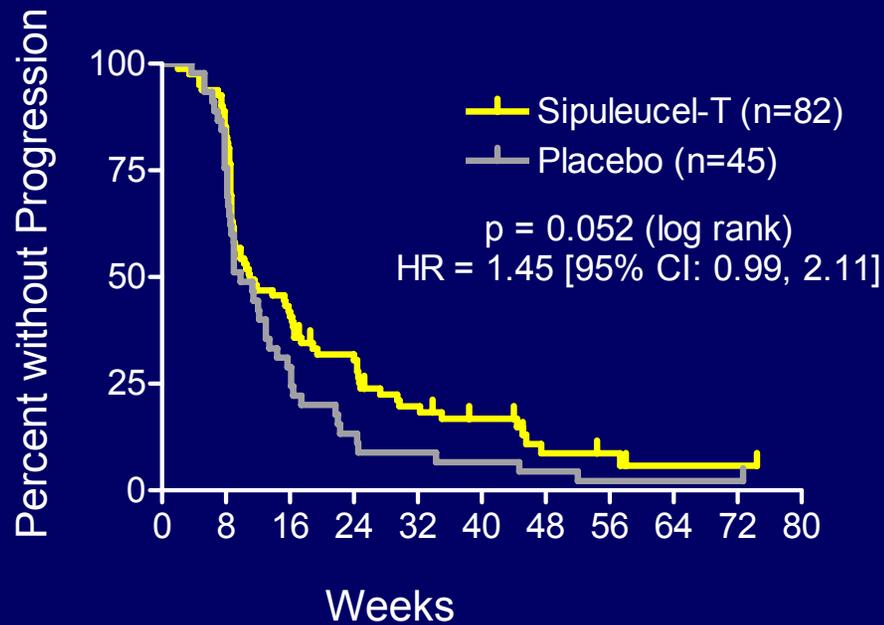
Disease Progression-Related Analyses

Study 1

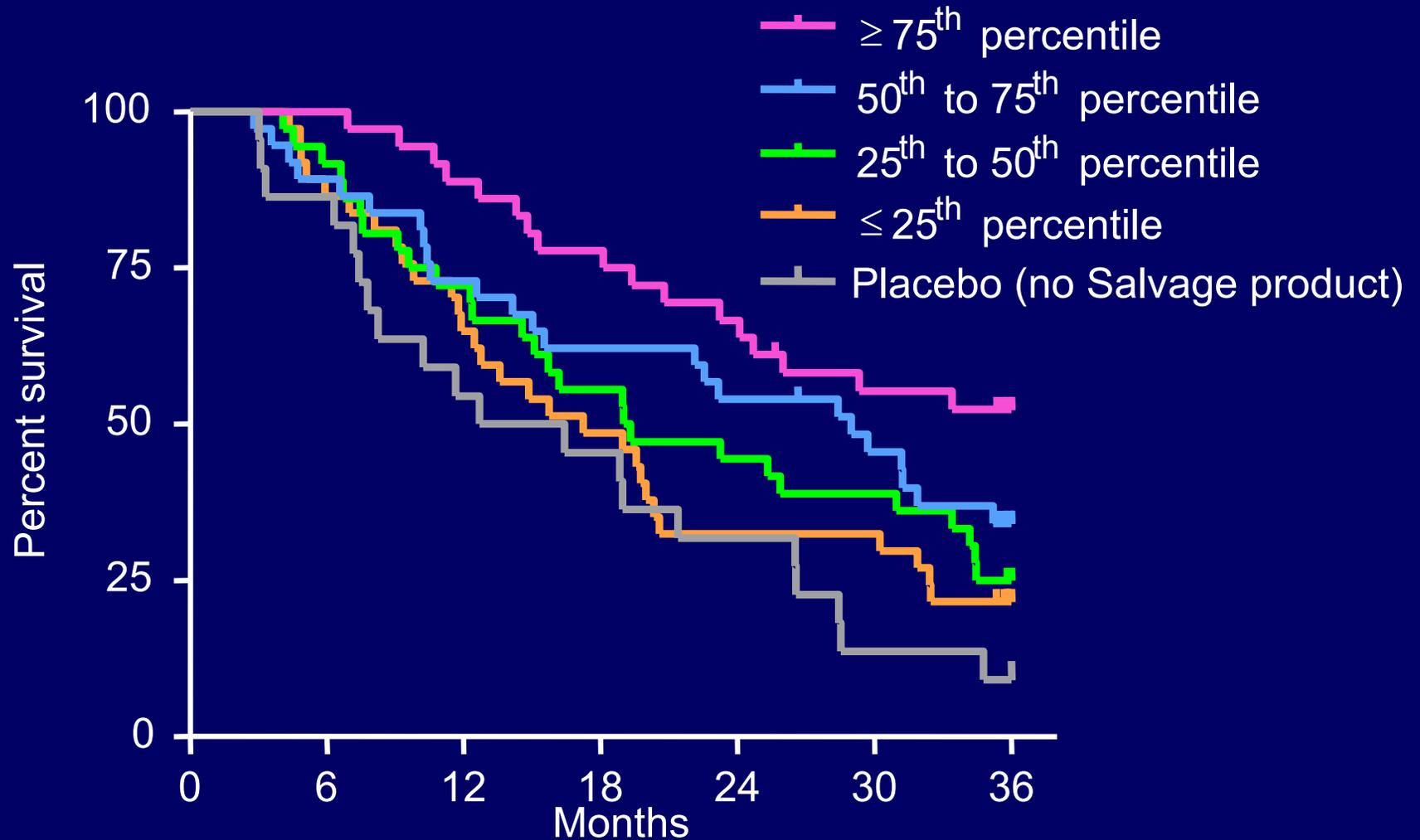
- Time to disease progression
- Time to objective progression
- Time to clinical progression
- Time to treatment failure
- Time to disease-related pain



Time to Disease Progression and Overall Survival, Kaplan-Meier Method, Study 1

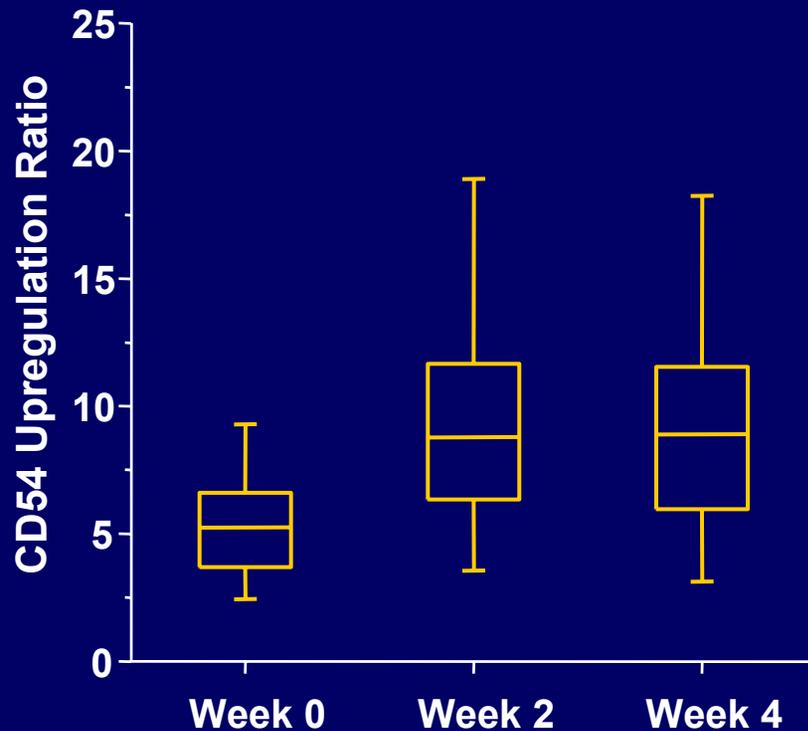


Sipuleucel-T Survival by Cumulative CD54 Upregulation in Quartiles with Placebo, Integrated Studies 1 & 2

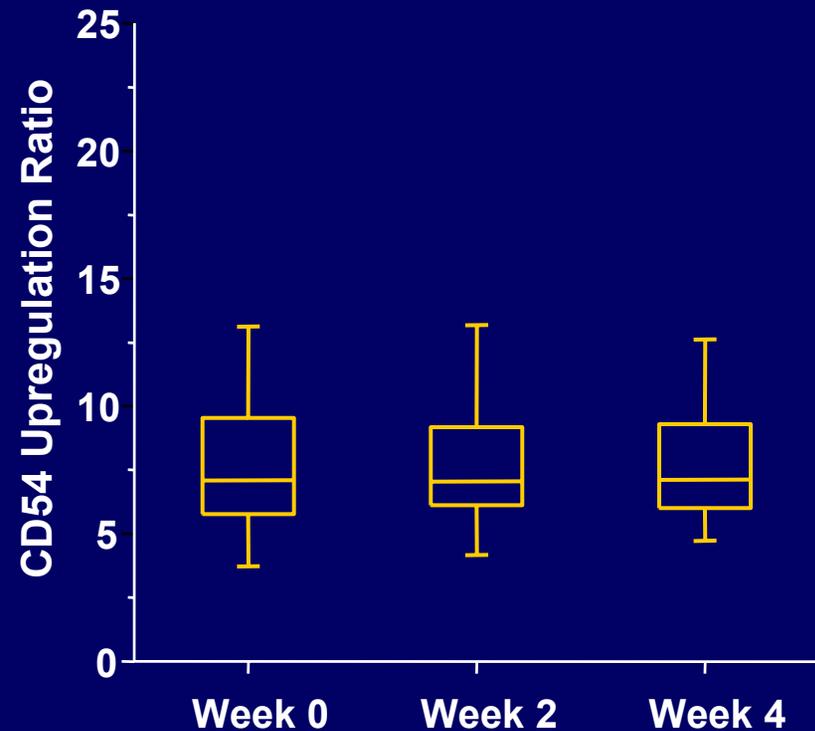


Salvage Product Does Not Have an Increase in CD54 Upregulation Ratios (Integrated Studies 1 & 2)

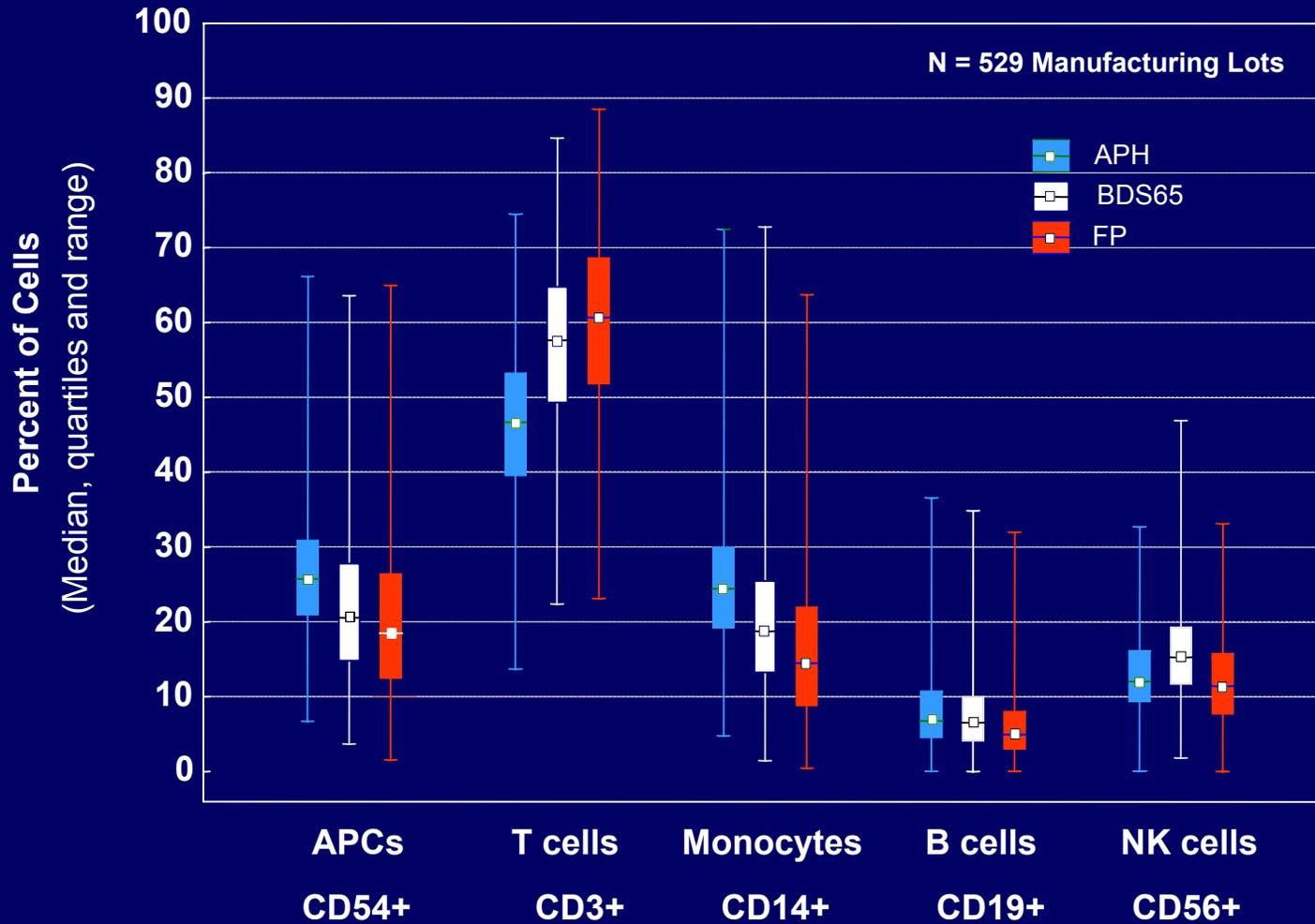
Sipuleucel-T



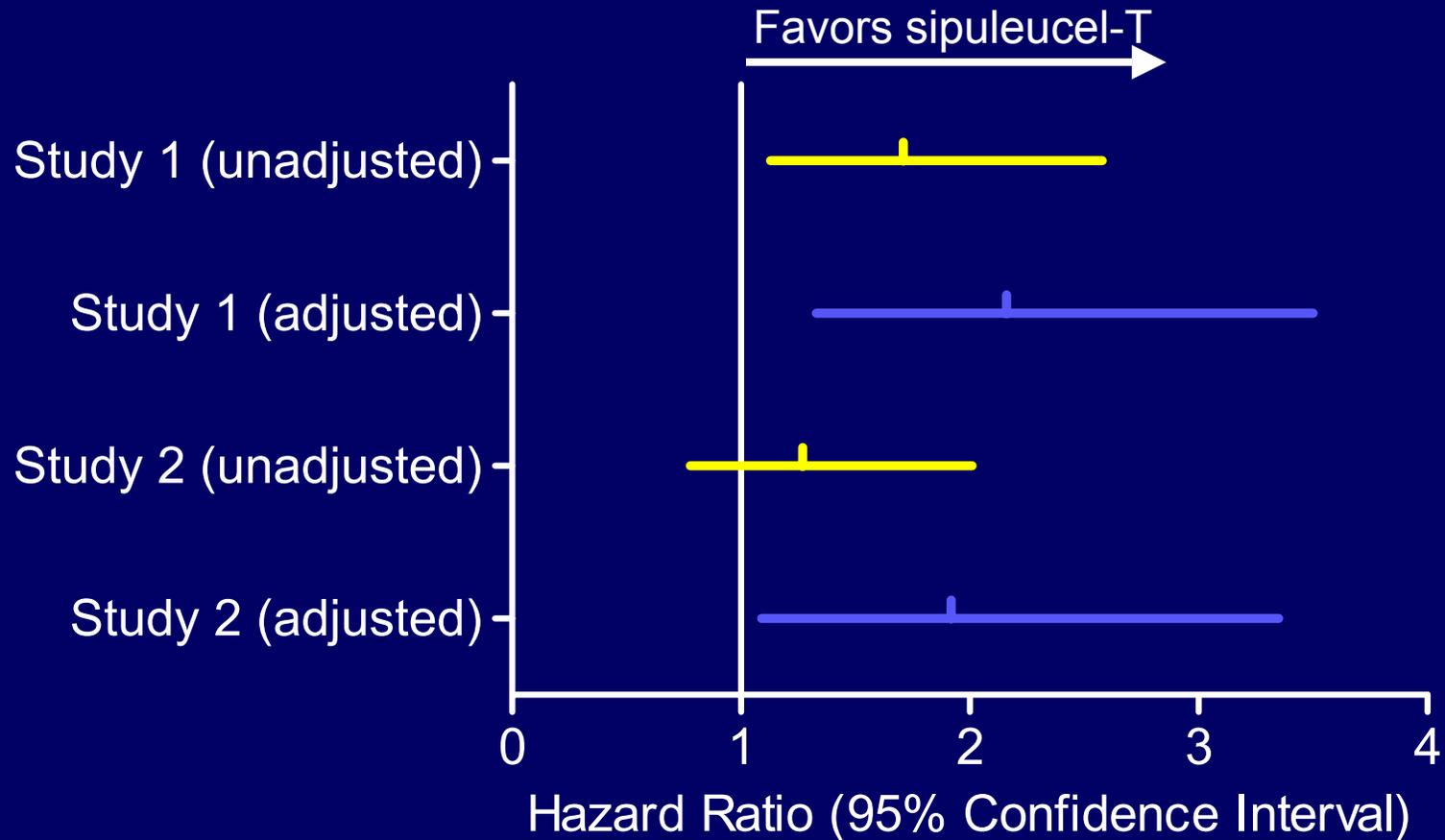
Salvage Product



Cellular Composition of Apheresis, Pre-Culture Cells and Sipuleucel-T



Overall Survival Study 1 and Study 2



Baseline Prognostic Comparisons by Study and by Treatment

	Study 1		Study 2	
	Sipuleucel-T	Placebo	Sipuleucel-T	Placebo
Median PSA (ng/mL)	46.0	47.9	61.3	44.0
Median LDH (U/L)	173.5	172.0	187.0	179.0
Bone & soft tissue involvement (%)	51.9	69.0	41.5	48.5
> 10 bone mets (%)	41.5	26.7	50.8	37.5
Weight	194.1	186.5	191.3	184.0

Potential Adverse Drug Reactions by Type of Study Product, All Studies (N = 669 Unique Patients)

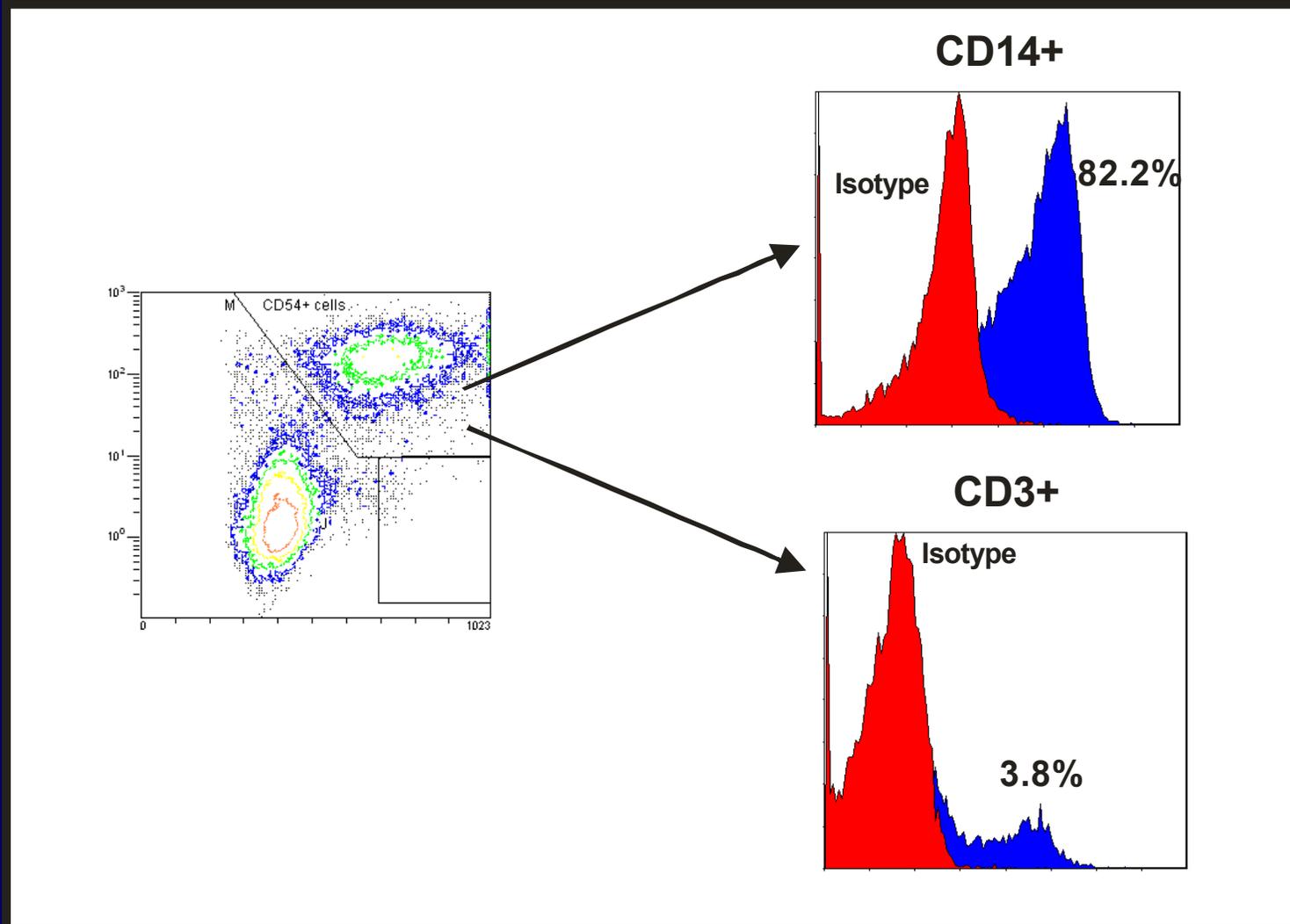
Preferred Term	Sipuleucel-T n = 233	Placebo n = 76	Blinded Product n = 345	Placebo/ Salvage n = 81	APC8026 n = 15
Chills	53.6%	7.9%	34.2%	17.3%	60.0%
Fatigue	37.8%	28.9%	35.7%	17.3%	20.0%
Pyrexia	31.3%	6.6%	22.9%	11.1%	26.7%
Headache	16.7%	6.6%	15.7%	1.2%	6.7%
Nausea	16.3%	7.9%	15.4%	14.8%	20.0%
Asthenia	13.3%	3.9%	7.5%	7.4%	13.3%
Dyspnea	11.2%	2.6%	6.1%	4.9%	6.7%
Vomiting	10.7%	2.6%	6.1%	6.2%	6.7%
Tremor	8.2%	0.0%	3.8%	1.2%	6.7%

Incidence of Cerebrovascular Events All Randomized Studies (As Randomized)

Events	N*	Sipuleucel-T	Placebo	OR (95% CI)
All Studies	461/231	3.9%	2.6%	1.52 (0.60, 3.89)
• AIPC Studies	345/172	4.9%	1.7%	2.92 (0.84, 10.10)
• ADPC Studies	116/59	0.9%	5.1%	0.16 (0.02, 1.60)

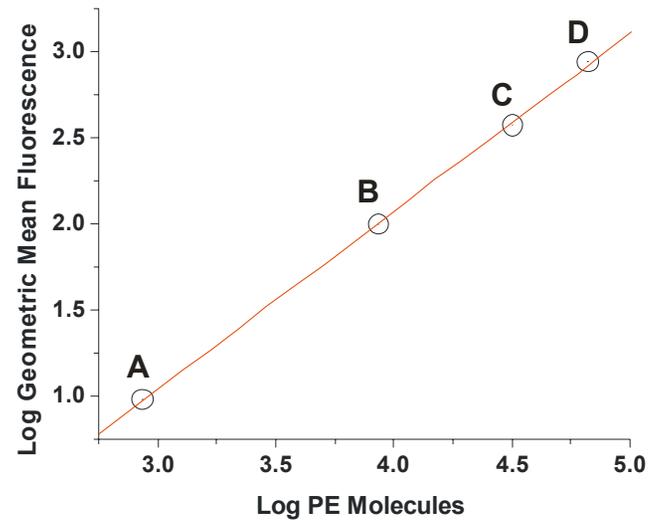
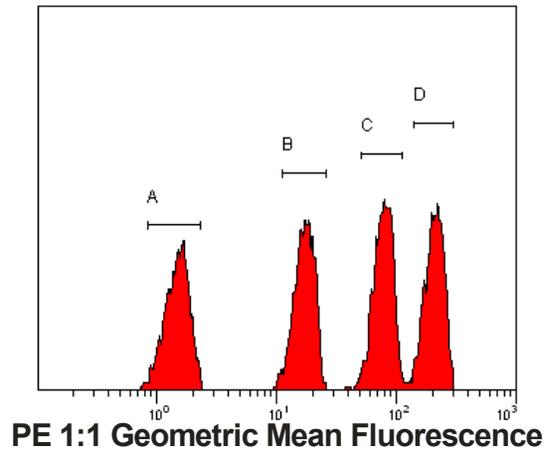
*Sipuleucel-T/Placebo

The Large CD54+ Cell Population Contains Very Few T Cells

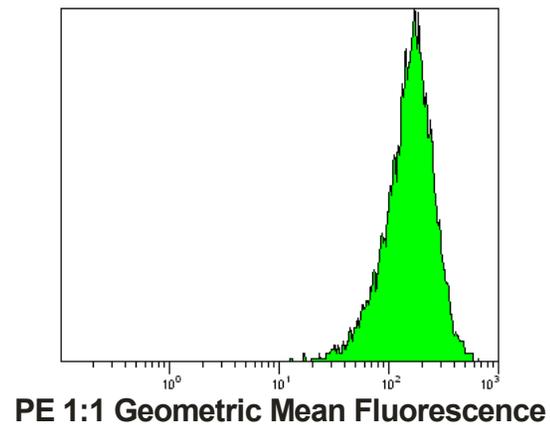
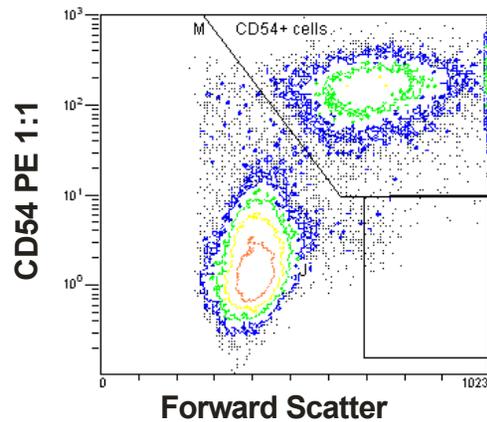


CD54 Sipuleucel-T Potency Assay

Quantibrite Bead PE Standard Curve

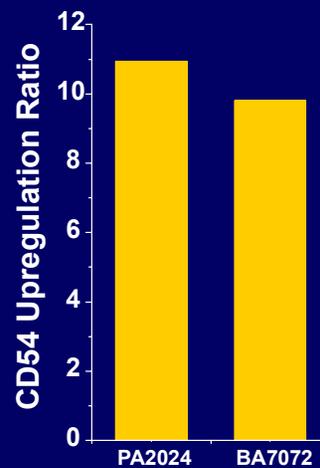


Large CD54+ Cells

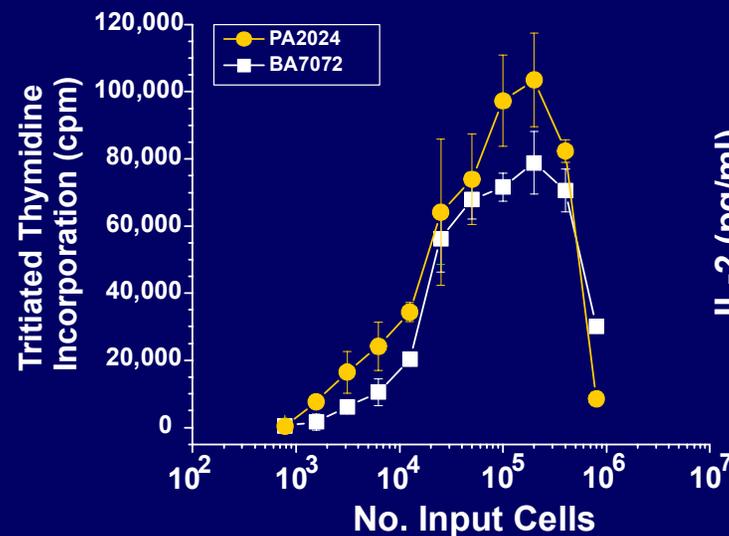


GM-CSF Activates APCs but Does Not Facilitate Antigen Processing and Presentation

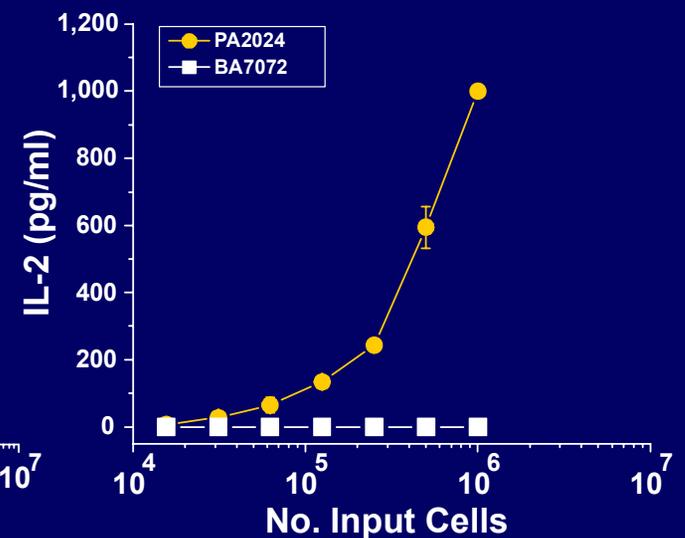
CD54 Upregulation



Allo-MLR



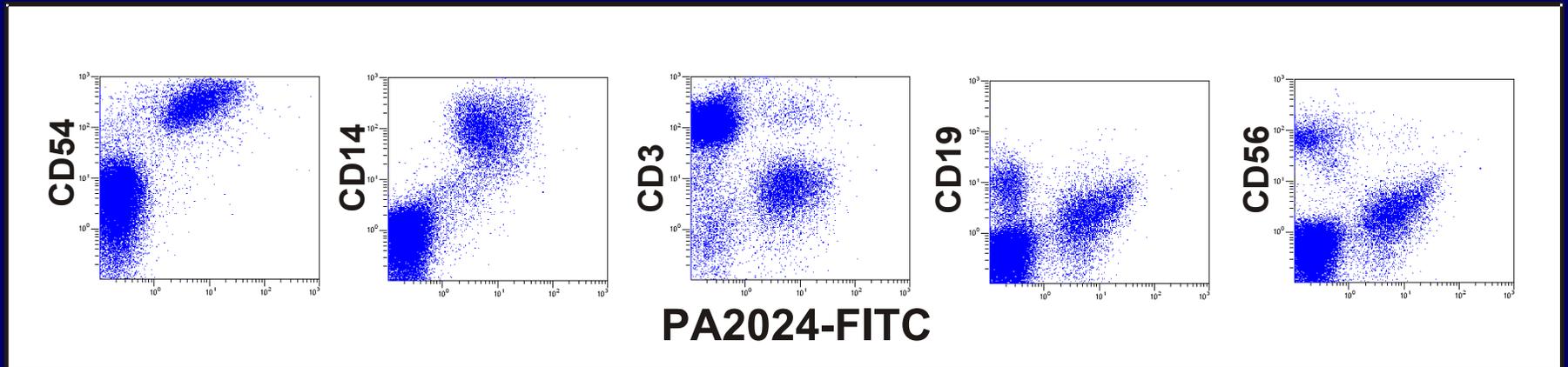
Antigen Presentation



PA2024-Specific Immune Responses Study 1

Antigen	Median of the Geometric Mean		p-value
	sipuleucel-T	Placebo	
Week 0 to Week 8	N=31	N=16	
PA2024	16.91	1.99	0.0004
Seminal PAP	1.07	1.90	0.2238
GM-CSF	1.31	1.09	0.7306
Week 0 to Week 16	N=14	N=8	
PA2024	13.22	0.91	0.0001
Seminal PAP	0.99	0.40	0.0890
GM-CSF	0.76	0.37	0.3650

CD54+ Cells Take Up PA2024



Antibody Responses to GM-CSF Following Treatment with Sipuleucel-T, Study 1

	sipuleucel-T N = 30 ≥ 16-fold increase in antibody titer	Placebo N = 17 ≥ 16-fold increase in antibody titer
PA2024	27 (90.0)	1 (5.9)
Seminal PAP	2 (6.9)	0 (0.0)
GM-CSF	14 (46.7)	0 (0.0)

T cell hybridomas are PAP-specific

