



Summary of Phase 3 IMPACT Trial Results Presented at AUA Meeting

Webcast Conference Call

April 28, 2009

» Nasdaq: DNDN

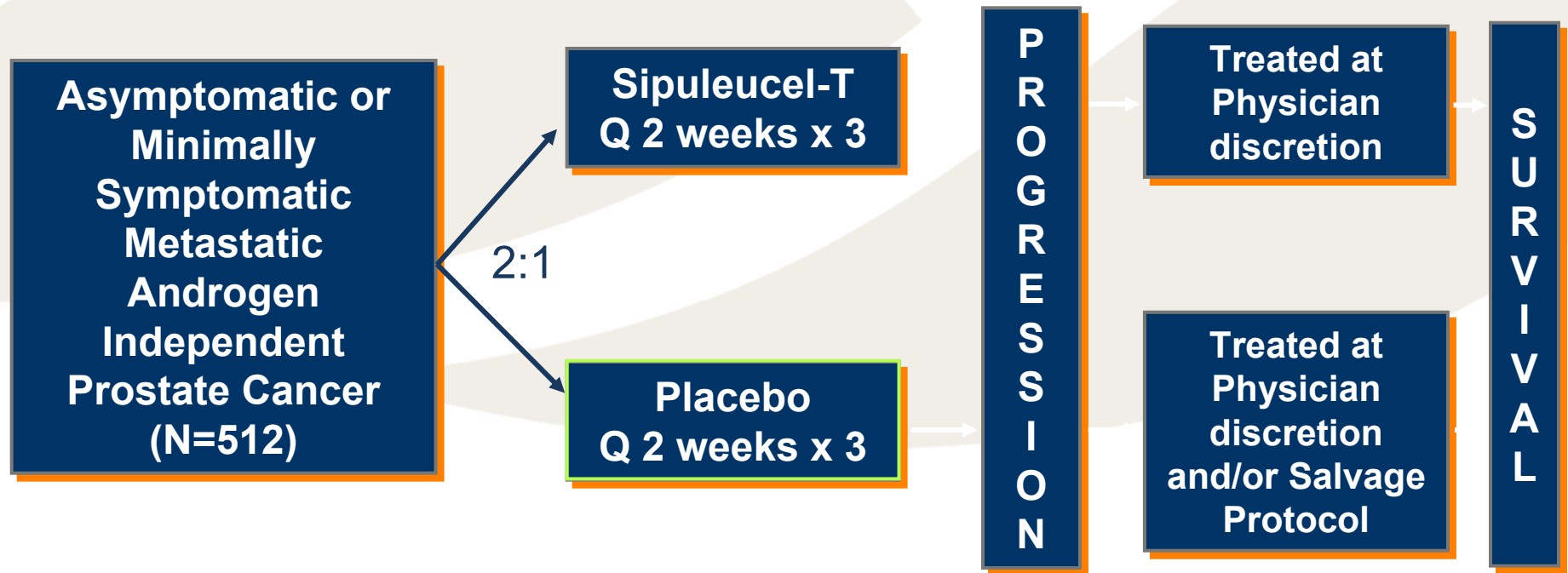
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## PROVENGE®

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

# Randomized Phase 3 IMPACT Trial

(IMMunotherapy Prostate AdenoCarcinoma Treatment)



Primary endpoint:

Overall Survival

Secondary endpoint:

Time to Objective Disease Progression

# IMPACT Phase 3 Study: Statistical Analysis Plan

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## » Stratification Factors

- » Bisphosphonate use
- » Primary Gleason score
- » Number of bone metastases

## » HR and P-values

- » Calculated from Cox model
  - Adjusted for PSA and LDH
- » 2 sided p-values
- » Log rank as sensitivity analysis

## » Analyses

- » Interim: one
- » Final:  $p < 0.043$  required for statistical significance

## Eligibility Criteria

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- » **Metastatic castrate resistant prostate cancer**
- » **Life expectancy of at least 6 months**
- » **Serum PSA  $\geq$  5.0 ng/mL**
- » **Castrate level of testosterone ( $<$  50 ng/dL) achieved via medical or surgical castration**
- » **Adequate hematologic, renal, and liver function**
- » **Negative serology for HIV 1 & 2, HTLV-1, and Hepatitis B & C**

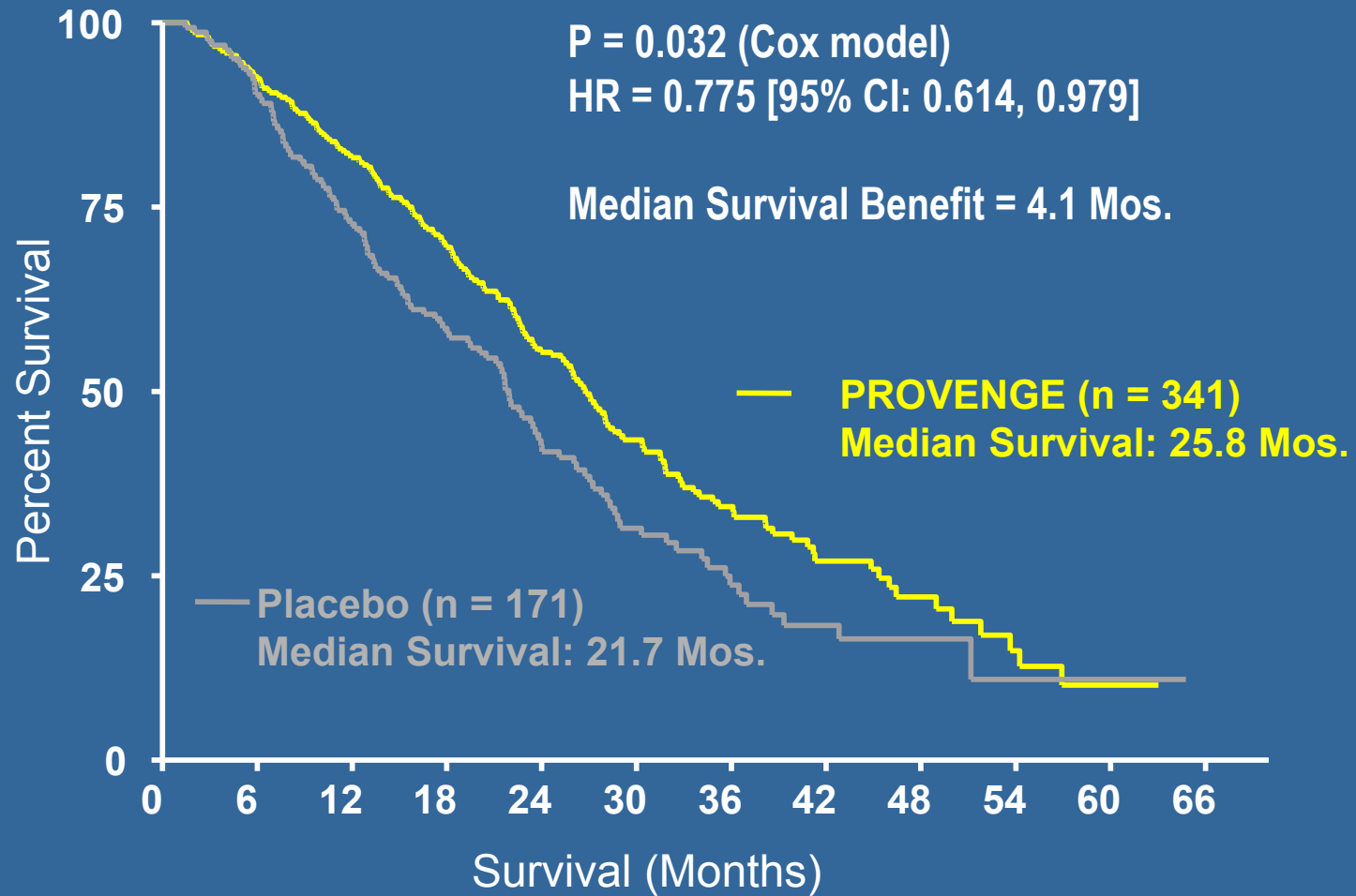
## Patient Demographics and Baseline Characteristics

	Sipuleucel-T (N = 341)	Placebo (N = 171)
Age, median yrs (range)	72 (49 – 91)	70 (40 – 89)
Race, white (%)	89.4	91.2
ECOG status, 0 (%)	82.1	81.3
Gleason Score ≤ 7 (%)	75.4	75.4
Disease localization		
Bone only (%)	50.7	43.3
Soft tissue only (%)	7.0	8.2
Bone & soft tissue (%)	41.9	48.5
>10 bone mets (%)	42.8	42.7
Bisphosphonate use	48.1	48.0
Prior docetaxel (%)	15.5	12.3

## Baseline Median Laboratory Values

	Sipuleucel-T (N = 341)	Placebo (N = 171)
Serum PSA, ng/mL	51.7	47.2
Serum PAP, U/L	2.7	3.2
Alk. Phosphatase, U/L	99.0	109.0
Hemoglobin, g/dL	12.9	12.7
LDH, U/L	194.0	193.0
WBC, 10 <sup>3</sup> /μL	6.2	6.0

# IMPACT Overall Survival: Primary Endpoint Intent-to-Treat Population





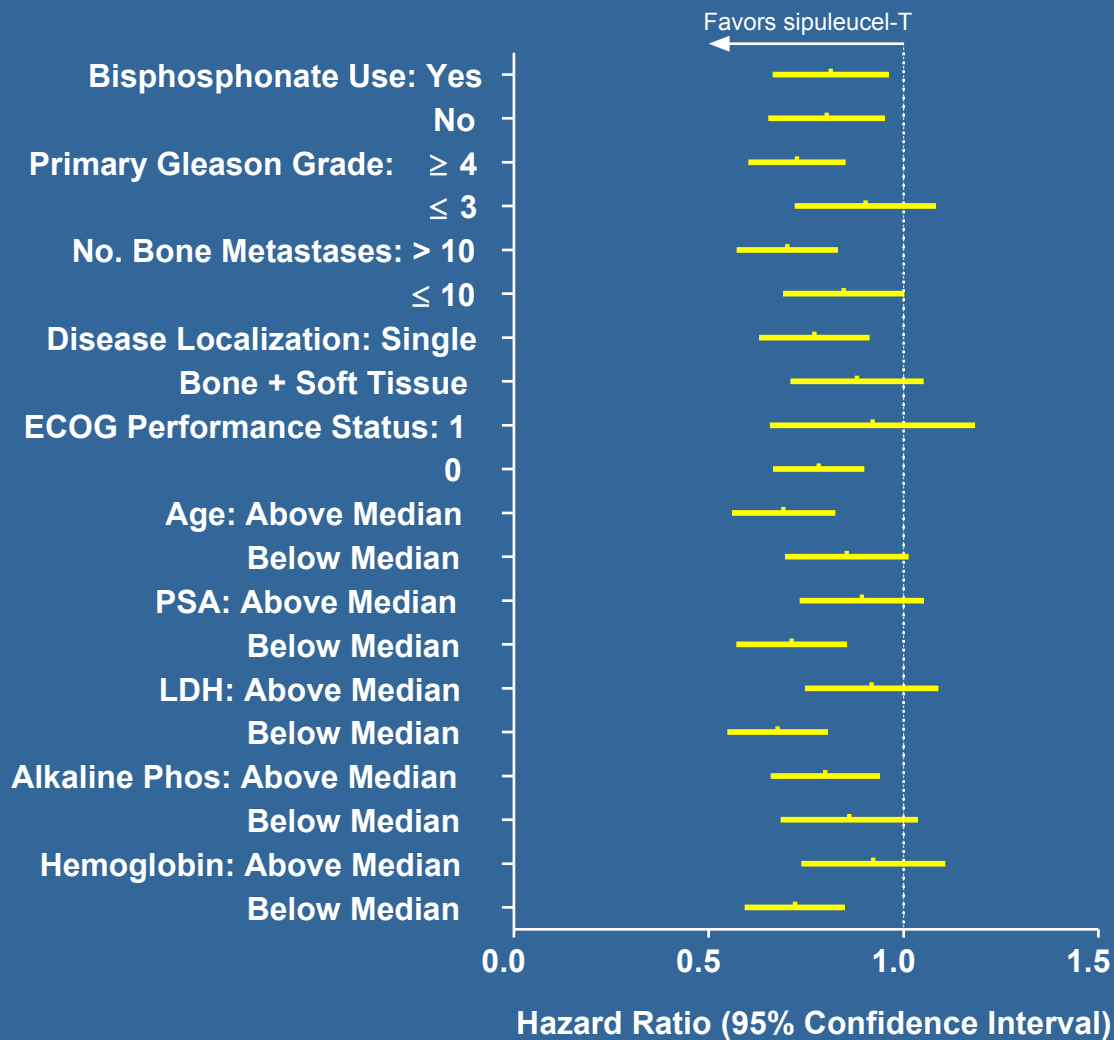
## Overall Survival Summary

	N	Survival Percentiles (months)		
		75%	50%	25%
<b>Sipuleucel-T</b>	<b>341</b>	<b>15.1</b>	<b>25.8</b>	<b>41.3</b>
<b>Placebo</b>	<b>171</b>	<b>11.0</b>	<b>21.7</b>	<b>35.6</b>

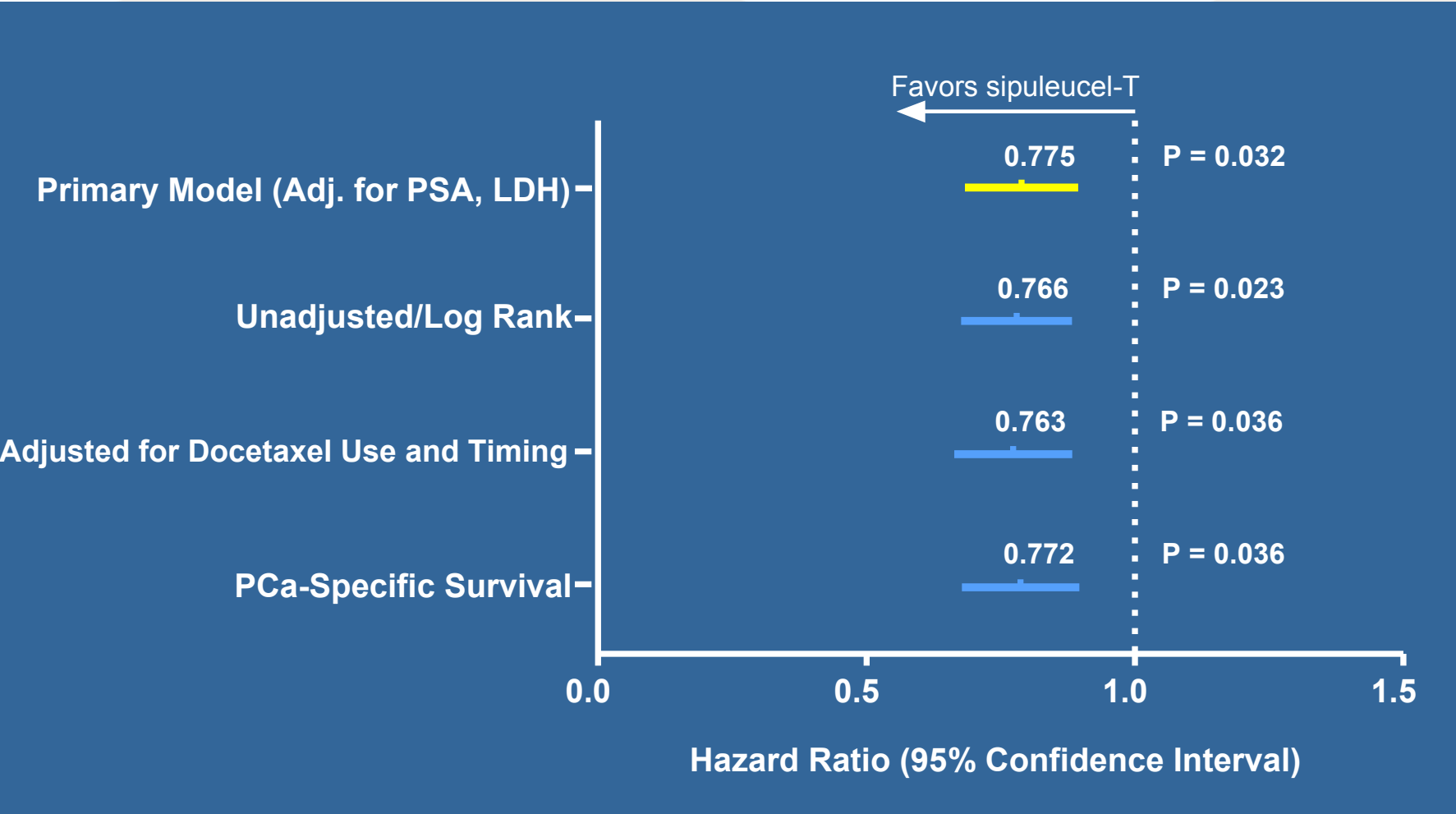
  

	% Survival (K-M estimates)		
	24 Mos.	36 Mos.	48 Mos.
<b>Sipuleucel-T</b>	<b>52.1</b>	<b>31.7</b>	<b>20.5</b>
<b>Placebo</b>	<b>41.2</b>	<b>23.0</b>	<b>16.0</b>

# Survival Consistency Between Population Subsets



# Survival Results Confirmed by Multiple Sensitivity Analyses



## Time to Objective Disease Progression

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» **Secondary endpoint**

» **Result**

» Independent radiologic review

» HR=0.951 (95% CI: 0.77,1.17); P=0.628 (log rank)

» **Consistent with other trials in advanced prostate cancer**

» **Difficult endpoint to measure reliably and doesn't correlate with overall survival**

**Most Common Adverse Events ( $\geq 5\%$ )  
Higher Rate in sipuleucel-T ( $p \leq 0.05$ )**

<b>Preferred Term</b>	<b>Sipuleucel-T N = 338 %</b>	<b>Placebo N = 168 %</b>
<b>Chills</b>	<b>54.1</b>	<b>12.5</b>
<b>Pyrexia (fever)</b>	<b>29.3</b>	<b>13.7</b>
<b>Headache</b>	<b>16.0</b>	<b>4.8</b>
<b>Influenza-like illness</b>	<b>9.8</b>	<b>3.6</b>
<b>Hypertension</b>	<b>7.4</b>	<b>3.0</b>
<b>Hyperhydrosis</b>	<b>5.3</b>	<b>0.6</b>

# Serious Adverse Events\*

## Safety Population

SAE Preferred Term	Sipuleucel-T N=338 %	Placebo N=168 %
Any SAE	24.0	23.8
Pyrexia	1.8	0.6
Cerebrovascular accident	1.8	1.8
Pulmonary embolism	1.2	0.0
Spinal cord compression	1.2	1.2
Nausea	0.9	1.2
Atrial fibrillation	0.9	0.6
Dehydration	0.9	0.6
Cardiac failure congestive	0.6	1.2
Pneumonia	0.6	1.2
Hematuria	0.6	1.2
Deep vein thrombosis	0.3	1.8
Renal failure acute	0.3	2.4

## Consistency Across Phase 3 Studies

	D9901* (N = 127)	D9902A* (N = 98)	IMPACT ** (N = 512)	Integrated** (N=737)
<b>Hazard Ratio</b>	<b>0.586</b>	<b>0.786</b>	<b>0.775</b>	<b>0.735</b>
<b>p-value</b>	<b>p = 0.010</b>	<b>p = 0.331</b>	<b>p = 0.032</b>	<b>p &lt; 0.001</b>
<b>Median Survival Benefit (months)</b>	<b>4.5</b>	<b>3.3</b>	<b>4.1</b>	<b>3.9</b>
<b>36-Month survival (%)</b>				
<b>sipuleucel-T</b>	<b>34%</b>	<b>32%</b>	<b>32%</b>	<b>33%</b>
<b>placebo</b>	<b>11%</b>	<b>21%</b>	<b>23%</b>	<b>20%</b>

\*Unadjusted Cox model & log rank

\*\*Cox model adjusted for PSA and LDH

## Conclusions of IMPACT Study

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- » **First active immunotherapy to demonstrate improvement in overall survival for advanced prostate cancer**
- » **Highly favorable benefit to risk profile**
- » **Short duration of therapy**
- » **Potential to create new treatment paradigm in oncology**
- » **Validates potential to apply platform across different cancers**





# Dendreon

*Targeting Cancer, Transforming Lives™*

***Dendreon has the potential to fundamentally  
change the way cancer is treated***

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