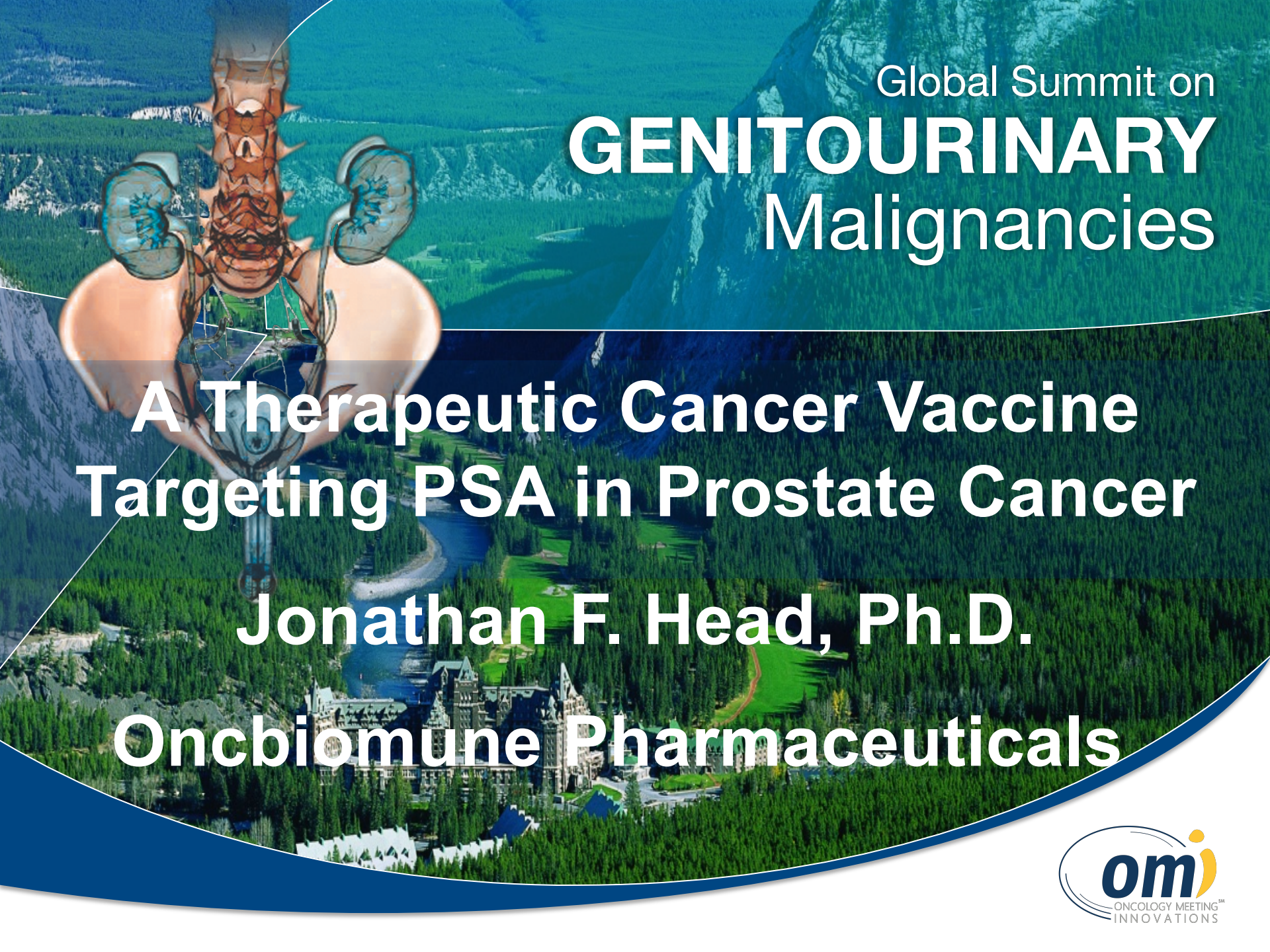
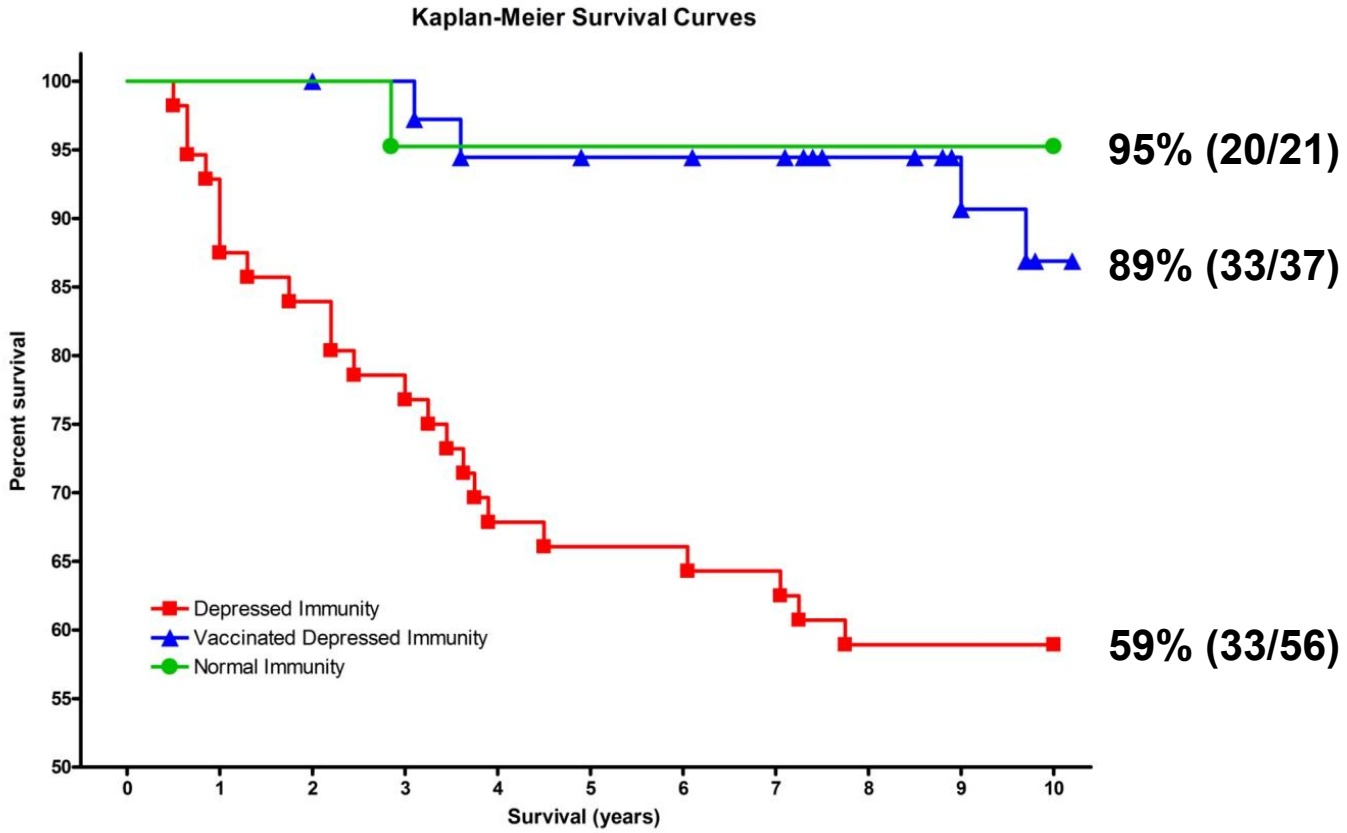
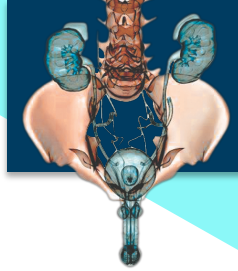

Global Summit on
GENITOURINARY
Malignancies
A Therapeutic Cancer Vaccine
Targeting PSA in Prostate Cancer
Jonathan F. Head, Ph.D.
Oncbiomune Pharmaceuticals
omi
ONCOLOGY MEETING INNOVATIONS

Survival Data from Adjuvant Breast Cancer Vaccine Study

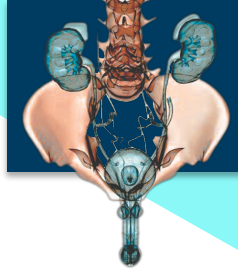
Initial Proof of Principal





From June 1993 to March 2011 Number of Patients Vaccinated by Type of Cancer

Cancer Type	Number of Patients
Breast	210
Prostate	26
Colon	4
Ovarian	4
Lung	4
Melanoma	2
Sarcoma	2
Stomach/Esophageal	1
Facial Skin	1
Tongue	1
TOTAL	255



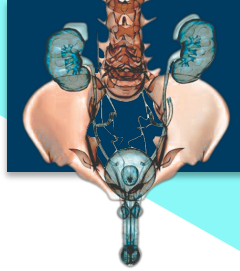
PSA Vaccine Components

Antigens

• PSA	50 micrograms
• CEA protein	2 micrograms
• CA 125 protein	1000 IU

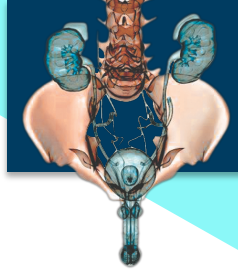
“Biological” Adjuvants

• IL-2	2 x 10^4 IU
• GM-CSF	16.7 micrograms



Patient Group

- Patients with rising PSAs between 4 and 10
- Biopsy confirmed nonpalpable prostate cancer
- No metastatic disease
- Gleason Score 5 or 6
- Willing to receive only the vaccine as primary therapy



PROTOCOL FOR VACCINATION OF PROSTATE CANCER PATIENTS

1. Before vaccination measure serum PSA

2. Vaccinate with PSA, CEA (2 ug) and CA-125 (1000 IU), and with adjuvant containing IL-2 (2 x 10^4 IU) and GM-CSF (16.7 ug). The volume of each agent will be 0.1 ml.

3. The vaccination schedule is as follows: Intradermal injection on weeks 1, 2, 3, 7, 11, 15 in same femoral triangle

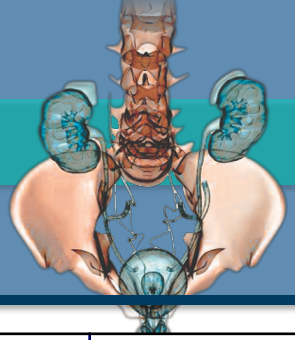
4. PSA will be measured again at 18 to 19 weeks.

5. Booster #7-12, every month, alternating IL-2 (11 million units) and PSA vaccine.

6. PSA will be measured again.

GLOBAL SUMMIT ON:

GENITOURNARY MALIGNANCIES

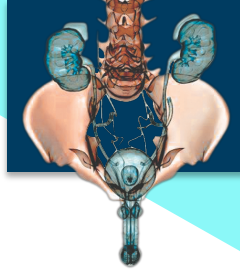


BANFF

CANADA

NOVEMBER 1 – 4

DIAGNOSIS	DATE OF 1ST VACCINE	PSA BEFORE VACCINE	PSA AFTER 6 VACCINES	PSA AFTER 12 VACCINES	LAST PSA (MONTHS)
Prostate Ca	06/13/97	4.10	2.40	2.50	3.50 (80)
Prostate Ca	04/22/99	1.04	0.60	0.66	0.90 (92)
Prostate Ca	07/27/99	6.80	6.40	only 6 vaccines	----
Prostate Ca	11/30/99	4.90	2.80	2.40	2.97 (42)
Prostate Ca	02/10/00	6.20	5.80	1.90	2.20 (65)
Prostate Ca	02/28/00	4.20	3.50	4.40	3.90 (18)
Prostate Ca	03/06/00	14.60	5.50	6.50	7.70 (49)
Prostate Ca	06/27/00	7.60	13.70	only 4 vaccines	----
Prostate Ca	08/08/00	4.00	4.93	seeds	----
Prostate Ca	03/22/01	8.95	10.60	17.19	----
Prostate Ca	05/21/01	7.20	5.41	7.30	6.00 (28)
Prostate Ca	06/04/01	4.55	7.02	4.17	10.80 (21)
Decrease PSA/ Total			8 of 12	6 of 9	7 of 8



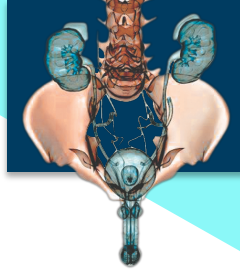
Navy Cancer Vaccine Program (NCVP) with OncBioMune

Naval Health Research Center (NHRC), San Diego, CA

Veterans Administration Medical Center (VAMC), La Jolla, CA

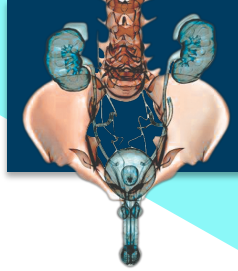
UCSD Medical School, La Jolla, CA

OncBioMune Pharmaceuticals, Baton Rouge, LA



NCVP Patient Group

Prostate Cancer Patients at Relapse (defined by rising PSA) after initial treatment (surgery, radiation or seeds)



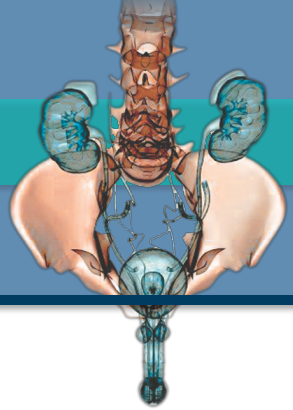
PSA Vaccine Components

Antigens

- PSA 50 micrograms

“Biological” Adjuvants

- IL-2 2×10^4 IU
- GM-CSF 16.7 micrograms



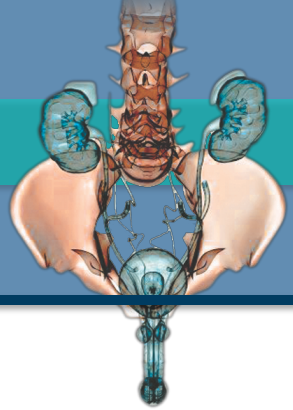
NCVP Phase 1a Clinical Trial

Vaccinate 20 patients to confirm minimal toxicity of the PSA vaccine

NCVP Phase 1b Clinical Trial

Enroll 28 additional patients

Add Boosters, #7-12, every month, alternating IL-2 (11 million units) and PSA vaccine

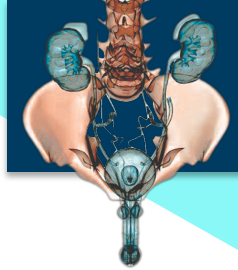


PRIMARY OBJECTIVE

- **To evaluate the safety and tolerability of the therapeutic prostate cancer vaccine.**

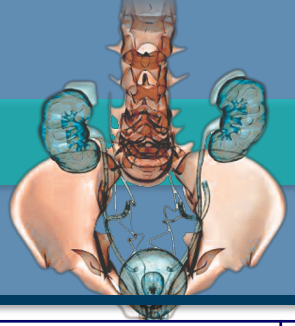
SECONDARY ANALYSIS

- **Vaccine-induced immune response**
- **Prostate-specific antigen doubling time (PSADT) will be determined before and after vaccination. An increase in PSADT >50% after vaccination will be considered clinically significant. The percent of subjects who achieve a clinically significant change will be calculated.**
- **Time to subsequent therapy, time to measurable disease, disease-specific survival, and overall survival will be calculated and compared with historical controls using Kaplan-Meier curves.**



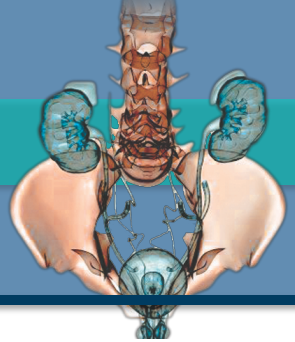
Immunity

PATIENT #	WEEK 1 LBA	WEEK 7 LBA AFTER 3 VACCINES	WEEK 19 LBA AFTER 6 VACCINES	WEEK 31 LBA	Increase in Immunity to PSA After Vaccine
1 P	------	0.88	1.77	1.22	------
2	1.56	1.72	0.91	1.65	YES
3	0.76	1.12	1.21	1.15	YES
4	2.08	1.41	1.52	2.06	NO
5 RP	1.60	1.75	1.64	1.15	YES
6	3.27	3.57	1.46	1.41	YES
7*	1.10	One Vaccine	------	------	------
8	1.16	1.31	1.93	1.50	YES
9 P	1.43	40.16	1.72	2.13	YES
10	0.82	1.19	1.00	1.53	YES
11 P	1.24	0.89	1.05	1.92	YES
12	1.49	0.90	0.93	0.97	NO
13*	Screen Fail	------	------	------	------
14	0.97	1.05	0.80	1.02	YES
15	0.82	0.96	1.11	1.31	YES
16	1.00	------	1.25	1.21	YES
17	1.76	------	------	------	------
18	1.12	------	------	1.64	YES
19*	Screen Fail	------	------	------	------
20 RP	1.14	------	------	0.73	NO
21	0.88	------	------	1.50	YES
22	1.03	1.13	------	0.88	YES
23	0.89	1.31	------	1.42	YES
		11/14	7/13	11/16	15/18

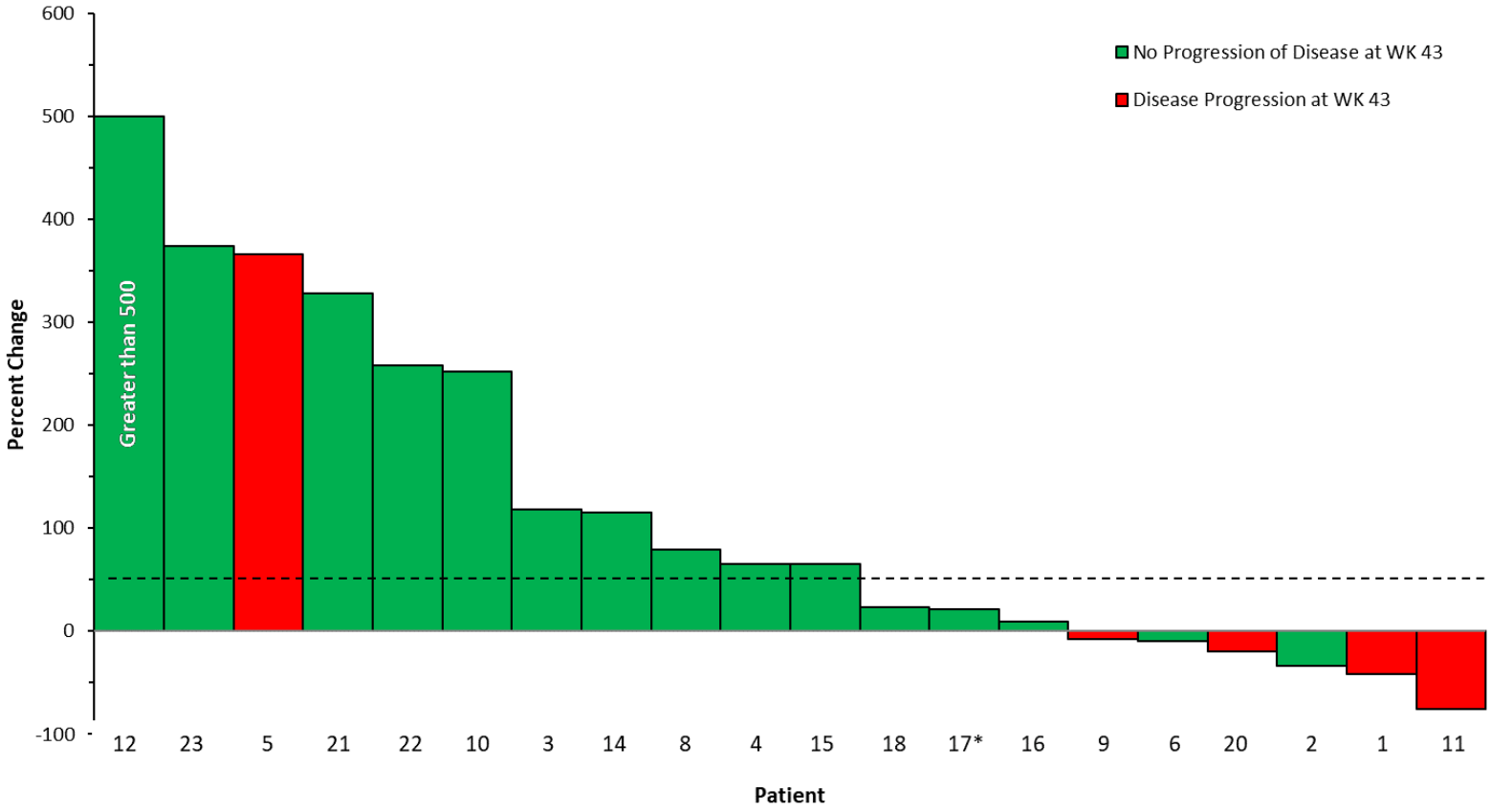


Patient Number	PSA Doubling Time Before Vaccine (Days)	PSA Doubling Time After Vaccine (Days)	Improvement in Doubling Time	Increase in Immunity to PSA After Vaccine
1 P	118	69	NO	-----
2	468	307	NO	YES
3	532	1158	YES	YES
4	298	492	YES	NO
5 RP	167	778	YES	YES
6	690	620	NO	YES
7*	One Vaccine	-----	-----	-----
8	364	650	YES	YES
9 P	76	70	NO	YES
10	264	930	YES	YES
11 P	614	149	NO	YES
12	389	SLOPE <0	YES	NO
13*	Screen Fail	-----	-----	-----
14	215	462	YES	YES
15	94	155	YES	YES
16	310	337	YES	YES
17	131	158	YES	-----
18	538	663	YES	YES
19*	Screen Fail	-----	-----	-----
20 RP	432	344	NO	NO
21	119	508	YES	YES
22	37	131	YES	YES
23	301	1427	YES	YES

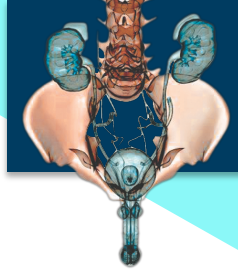
*Patient Withdrawn P is PSA Progression RP is Radiological Progression 14/20 15/18



Percent Change in PSA Doubling Time



*On Another Clinical Trial

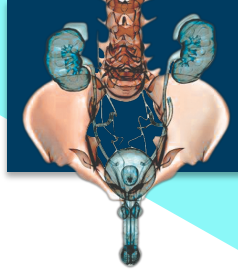


PROGRESSION DATA

PATIENT #	WEEK 19 FOLLOW-UP AFTER 6 VACCINES	WEEK 31 FOLLOW-UP	WEEK 43 FOLLOW-UP
1 P			
2			
3			
4			
5 RP			
6			LTF
8			
9 P			
10			
11 P			
12			
14			
15			
16			
17		On Another Clinical Trial	
18			
20 RP			
21			LTF
22			
23			
Stable/ No Progression	16 of 20	15 of 19	12 of 17

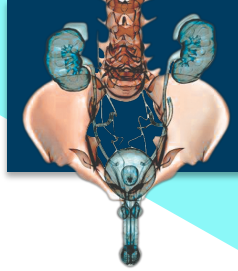
Green = Stable/No Progression Red = Progression LTF = Lost to Follow-up

P = PSA Progression RP = Radiological Progression



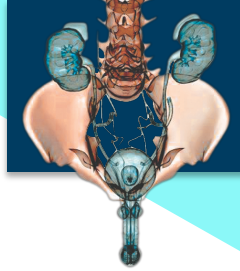
CONCLUSIONS

- Twenty patients have received all 6 vaccines.
- None of the 20 patients who have received all 6 vaccines have had a Serious Adverse Event (SAE).
- None of the 20 patients who have received all 6 vaccines have had a Dose Limiting Adverse Event (DLAE).
- Fifteen of the 18 patients who have received 6 vaccines have had increased immune responses to PSA as determined with a Lymphocyte Blastogenesis Assay.
- Fourteen of the 20 patients who have received 6 vaccines have had an increase in PSA doubling time.
- Five of 17 patients have progressed at 43 weeks.



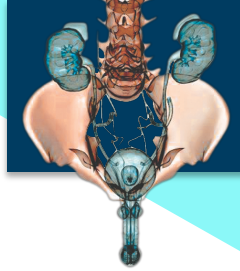
Phase 1 Highlights

- **Trial at University of California San Diego Moore's Cancer Center and the Veterans' Hospital, La Jolla, CA**
- **Trial in patients with recurrent disease**
- **20 biochemically progressing patients enrolled, 5 dropped out of study for progression at 43 weeks (3 PSA, 2 radiological)**
- **OncBioMune Pharmaceuticals submitted to the FDA a Phase 2 Clinical Trial due to lack of toxicity of the PSA therapeutic vaccine**



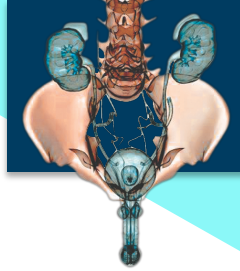
Progress

- Recombinant PSA has been manufactured cGMP
- Engaged Theradex as our CRO for putting together our IND submission and as Medical Monitor
- FDA IND approved
- UCSD Medical School IRB approved
- Fully funded Phase 1 Clinical Trial initiated 1st quarter 2013 and successfully reached Primary Endpoint
- FDA has approved Phase 2 Protocol
- The Phase 2 Protocol has been approved by the IRB at Beth Israel Deaconess Medical Center/Dana-Farber Cancer Institute of Harvard Medical School.



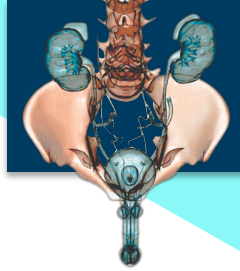
Phase 2

- The Study will be hosted at Beth Israel Deaconess Medical Center (Contact: Rupal Bhatt, MD/PhD)
- Study Sponsor: OncBioMune Pharmaceuticals
- Investigators: Rupal Bhatt, MD/PhD; David Einstein, MD; Glenn Bubley, MD (Med Onc)
- Group/Participating Institutions: Harvard Medical School (BIDMC, DFCI/BWH)
- Patient Number will be 120 (80 vaccinated prostate cancer patients and 40 control prostate cancer patients)
- Patient population will be in the active surveillance category, where standard surgical or radiation therapy are not yet indicated



Phase 2

- **The Study will be hosted at Urology Clinic of North Texas; Dallas, TX**
- **Study Sponsor: OncBioMune Pharmaceuticals**
- **Principal Investigator: James S. Cochran, M.D., D.A.B.U., F.A.C.S.**
- **Patient Number: 30 prostate cancer patients will be vaccinated with ProscaVax**
- **Patient population will be biochemical progression (rising PSA) after standard surgical or radiation therapy**



CONTACT

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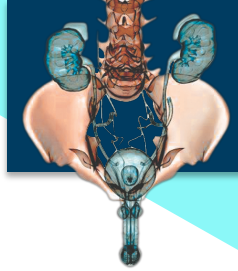
Baton Rouge, LA 70809
(225) 227-2384



GLOBAL SUMMIT ON:
GENITOURINARY
MALIGNANCIES

KEY INCLUSION CRITERIA: Phase 1a and 1b Clinical Trial

- **Adenocarcinoma of the prostate.**
- **Rising serum PSA levels documented by 3 values over the last 6 months prior to study enrollment. Each value must be >2 weeks from the previous value.**
- **Patients with rising PSA must have had either 1) prior definitive therapy including surgery or radiation therapy (hormone-naïve, defined as hormone-naïve patients and patients who received hormone therapy in the past who currently have total testosterone >50 ng/dL), OR 2) hormone suppressive therapy as documented by surgical castration or a serum testosterone value <50 ng/dL (hormone-independent). Patients must have completed these therapies for at least 6 months but no longer than 20 years prior to enrollment.**
- **PSA value within 4 weeks of starting therapy <20 ng/mL for hormone-naïve (defined as hormone-naïve patients and patients who received hormone therapy in the past who currently have total testosterone >50 ng/dL) patients or <60 ng/mL for hormone-independent patients.**
- **NO radiographically measurable disease.**