

## **A Phase 1 Trial of PSA-Activated PSA-PAH1 Therapy for Locally Recurrent Prostate Cancer without Metastases after Primary Radiation Therapy**

### **INCLUSION CRITERIA**

1. 18 years of age or older
2. Histologically proven prostate adenocarcinoma
3. Completed a full course of definitive external beam radiation or definitive brachytherapy (but not both) as primary therapy for diagnosed prostate cancer at least one year prior to enrollment
4. Subject must have at least one available PSA measurement that was taken 60 days or more following their primary therapy, but no later than 2 months prior to their screening visit (this measurement will serve as the first time point for computing a screening value for PSA doubling time)
5. Subjects PSA doubling time at screening must be > 3 months (this doubling time will be computed by comparing the earliest available PSA that is 60 days or more following the subject's primary therapy but no later than 2 months prior to their screening visit, to the PSA measurement obtained during the screening visit)

#### Within one year prior to enrollment

6. Demonstrated "biochemical failure," as determined by three consecutive increases in PSA at least 2 weeks apart (ASTRO Consensus statement 1997 (Appendix A))
7. Multiple site biopsy-confirmed local recurrence of prostate cancer

#### Within 3 months prior to enrollment

8. No evidence of metastatic disease including no bone metastases on bone scan, or any lymph node, lung, liver or soft tissue metastases on a CT or MRI scan or any other evidence of metastatic disease
9. No receipt of androgen ablation therapy (Note: Subjects may have received androgen ablation therapy in the past, but not within 3 months prior to enrollment. No subject will be removed from androgen ablation therapy prior to this trial to permit/facilitate eligibility for this trial.)

#### Within 30 days prior to enrollment

10. Prostate gland weighing less than 40 g estimated on the basis of CT/ultrasound data
11. Serum testosterone above castrate range (> 1 ng/dl)
12. PSA level less than 20 ng/ml
13. Eastern Cooperative Oncology Group (ECOG) score of 0-2
14. Written informed consent
15. Adequate organ function as evidenced by:
  - Serum creatinine < 1.5 upper limit of normal (ULN)
  - Total serum bilirubin < 2 x ULN
  - Transaminases (SGOT and SGPT) < 2.5 x ULN
  - Hb > 10 g/dl
  - Absolute neutrophil count > 1500/uL
  - Platelets > 100,000/uL
  - Lymphocyte count > 1000/uL
  - PT/PTT within normal limits

## **EXCLUSION CRITERIA**

1. Any history of active malignancy other than prostate cancer
2. Have active viral, bacterial or fungal infections that require systemic therapy
3. Prior biological, immunological or chemotherapy for prostate cancer
4. Receiving concurrent medication for prostate cancer
5. Received as primary therapy for prostate cancer, definitive external beam radiation and concomitant brachytherapy
6. Prior history of metastatic prostate cancer
7. Treatment with other investigational therapies within 12 months prior to enrollment that could produce a compromised immune system, or receipt of immunosuppressive drugs including corticosteroids or ketoconazole within 1 month prior to enrollment, or a history of immunodeficiency disease
8. Recurrence of prostate cancer within 6 months after initiation of primary radiotherapy
9. Active heart, liver, lung, renal disease, active infection or other serious uncontrolled disease
10. Positive antibody test during screening for HIV-1, HIV -2, HTLV-1, HTLV-2, Hep B or Hep C
11. Unable or unwilling to return for required visits and follow-up examinations
12. Have a chronic indwelling Foley catheter for obstructive uropathy
13. Received salvage external beam radiotherapy and/or salvage seed brachytherapy prior to enrollment
14. Received prior treatment with PSA-PAH1 (subjects may not be redosed under this protocol)
15. Men unwilling to use condoms for the duration of the study (3 months) to prevent a pregnancy, and to avoid semen contact with their partner

Not mentioned:

Can not have had prostatectomy or cryosurgery of the prostate.