Phase II Study of PROSTVAC®-VF for Androgen-Independent Adenocarcinoma of the Prostate

THERION BIOLOGICS

Title:

A Phase II Randomized, Double Blind, Controlled Study to Evaluate the Safety and Efficacy of PROSTVAC®-VF/TRICOM™ in Combination with GM-CSF in Patients with Androgen-Independent Adenocarcinoma of the Prostate

Primary Endpoint:

Progression-free survival (PFS) defined as the proportion of patients who remain alive and progression-free at the end of the study (Day 168). Progression is determined via bone and/or CT scan results, and is defined following modified RECIST criteria.

Secondary Endpoints:

1. Safety; 2. Time to progression; 3. Time to onset of tumor-associated pain; 4. Effect on PSA levels.

PROSTVAC®-VF:

PROSTVAC-VF is an investigational cancer vaccine. The vaccine was developed based on the theory that a T-cell mediated immune response can target and destroy cancer cells expressing specific tumor-associated antigens (TAA). This clinical study will test the clinical safety and efficacy of PROSTVAC-VF in patients with prostate cancer.

The vaccine comprises two separate vaccine vectors, each of which contain genes encoding human PSA and three costimulatory molecules (LFA-3, ICAM-1, and B7.1).

Protocol Outline:

Eligible patients are randomized 2:1 active vaccine to empty vector. PROSTVAC-V (prime) is administered on Day 0, and PROSTVAC-F (boost) is administered every other week for a month and monthly thereafter for four months.

Inclusion Criteria:

- Male patients ≥ 18 years of age who have been vaccinated against smallpox;
- Evidence of metastatic disease including either of the following:
    - Lymph node metastases measurable (> 1cm) by CT and/or;
    - Bone metastases evaluable by bone scan;
- Refractory to hormone therapy defined by: evidence of two consecutive increases in PSA documented over a previous reference value, the first occurring a minimum of 1 week from the reference value, with one value of at least 5 ng/mL;
- Castrate testosterone levels < 50 ng/dL consistent with orchiectomy or continuous treatment with GnRH agonists for the duration of the trial;
- Gleason Score of 7 or lower at initial diagnosis.

Exclusion Criteria:

- Concurrent therapy such as palliative radiation or opioid analgesics for tumor-associated pain;
- Antiandrogen therapy [such as Casodex (bicalutamide), Nilandron (nilutamide), or Eulexin (flutamide)] or other hormone therapy (such as Ketoconazole) within 42 days of registration;
- Prior chemotherapy for prostate cancer;
- Metastasis to organ systems other than lymph nodes and bone;
- Prior or concurrent extensive eczema or acute, chronic or exfoliative skin disorders;
- Concurrent malignancy, unless treated and disease-free for > 2 years.

Please note, there are additional eligibility criteria