# ProstAtak Immunotherapy Trial for Localized Prostate Cancer Patients (PrTK03)

***RECRUIT:***

Localized intermediate or high-risk prostate cancer patients, who are choosing…

## Radiation Therapy:

Intermediate Risk w/ at least one of the following:

▶PSA 10-20 ng/ml ▶Gleason score = 7 ▶T2b-T2c

High Risk: w/ **ONLY ONE** factor:

▶PSA> 20 ng/ml ▶Gleason score 8-10 ▶T3a

***PSA:** One PSA evaluation in the last 6 months.

***Biopsy:** Positive biopsy in the last 12 months.

**Radiation:** Standard external beam radiation with no lymph node radiation, with or without short term ADT (≤6 months). See protocol for more details.

*If these evaluations are slightly older, discuss with Sponsor, as they may still be acceptable for enrollment with a minor variance.

***Frequently Asked Questions:***

**Can patients on ADT be in this trial?**

Yes, as long as the total duration of ADT does not exceed 6 months. ADT is optional but must be decided before enrollment.

**Is the use of rectal hydrogel spacer allowed on the study?**

If the use of a rectal hydrogel spacer is determined to be clinically appropriate for a particular patient, it would not preclude them from enrollment in the study. However, once the spacer is in place, injections must be performed transperineally.

**Can patients with an autoimmune disease (e.g. rheumatoid arthritis or psoriasis) be on the study?**

Yes, however systemic immunosuppressive therapy is an exclusion criterion since the mechanism behind ProstAtak involves immune stimulation. If you have questions about a patient or a particular medication, please contact Sponsor.

**What are the most common clinical side effects that can be expected from the experimental treatment?**

- The most common side effects were flu-like symptoms (fever, chills, tiredness and body aches) within 2 days after injection. Ibuprofen or acetaminophen helps to minimize these symptoms.
- Valacyclovir can cause some mild GI symptoms (nausea, vomiting). It is important for patients to drink adequate of fluids while taking valacyclovir to avoid dehydration and possible kidney injury.

## Patient Enrollment Guide for ProstAtak Immunotherapy Trial (PrTK03)

*A Complete submission checklist can be found on page 2 of the CRF Submission Schedule.*

**Submit at time of enrollment:**

✓ Eligibility Form (**EC**).
Include an attached copy of:
- Pathology and PSA Reports: Performed within 12 and 6 months of enrollment date respectively.
- H&P, DRE, ECOG, & Lab Report (CBC, differential, platelets, creatinine, AST, ALT, alkaline phosphatase, billirrubin): Performed within 4 weeks prior to first injection.
- For High Risk patients: Bone Scan and Pelvic CT or MRI.

✓ Signed Consent Form.

**Submit when available:**

✓ Quality of Life Form (**QL**).

✓ Pathology slides for central archiving (**PT and slides**).

✓ Blood collection for research (optional) (**BS**).

**Schedule Injections.**

ProstAtak/placebo Injection Timeline:

✓ **1st injection:** At least 2-8 weeks prior to start radiation.

✓ **2nd injection:** On the day of or up to 3 days prior to start radiation and at least 2 weeks after 1st injection.

✓ **3rd injection:** 2-3 weeks after 2nd injection.

*A Schedule planner is available as a tool to help make sure dates are within protocol specifications or contact Sponsor for further assistance.*

*The prodrug (valacyclovir) will be given for 14 days after each injection starting the day after the injection. Subsequent injections can be done on the last day of valacyclovir of the previous course.

Submit CRFs and supporting documents to Sponsor, Inc via:
Fax (617-916-5444) or email (crf@candeltx.com).
Phone: (617)-916-5445