ULYSSES Immunotherapy Trial for ACTIVE SURVEILLANCE Prostate Cancer Patients (PrTK04)

RECRUIT:

Existing AND Newly Diagnosed prostate cancer patients, who are choosing…

ACTIVE SURVEILLANCE:

Low risk w/ all of the following:

▸PSA <10 ng/ml ▸Gleason score ≤ 6 ▸T1-T2a

Intermediate Risk w/at least one of the following:

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

High Risk w/ **ONLY ONE** of the following:

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

***PSAs:** Two PSA evaluations at least 4 weeks apart and one within 4 weeks prior to the first injection.

***Biopsy:** Positive biopsy in the last 6 months.

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

Frequently Asked Questions:

If the patient had or is planning to undergo other treatment for prostate cancer, can he still be eligible for this trial?

No, prior treatment (except TURP) or planning treatment within next 12 months are excluded.

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.

Can a patient actively taking 5-alpha reductase inhibitors (e.g. finasteride or Dutasteride) be on this trial?

No, because these medications can affect PSA levels that are being analyzed as part of the endpoint of this trial. However, if a patient has recently stopped or agrees to suspend this medication, he may qualify after a wash out period.

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 ULYSSES Immunotherapy Trial for ACTIVE SURVEILLANCE Prostate Cancer (PrTK04)

advantagene, Inc.

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 report: Performed within 6 months of study enrollment.
- Two PSA reports at least 4 weeks apart and one within 4 weeks prior to the first injection.
- H&P, DRE, ECOG, & Lab Report (CBC, differential, platelets, creatinine, AST, ALT, alkaline phosphatase, bilirubin): Performed ≤ 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**)

Schedule Injections

AdV-tk/placebo Injection Timeline:

✓ **1st injection**: Within 4 weeks of baseline clinical and laboratory evaluations.

✓ **2nd injection:** 2-3 weeks after 1st injection.

A patient treatment schedule is available to help inform patients about study treatment and follow up dates.

*The 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