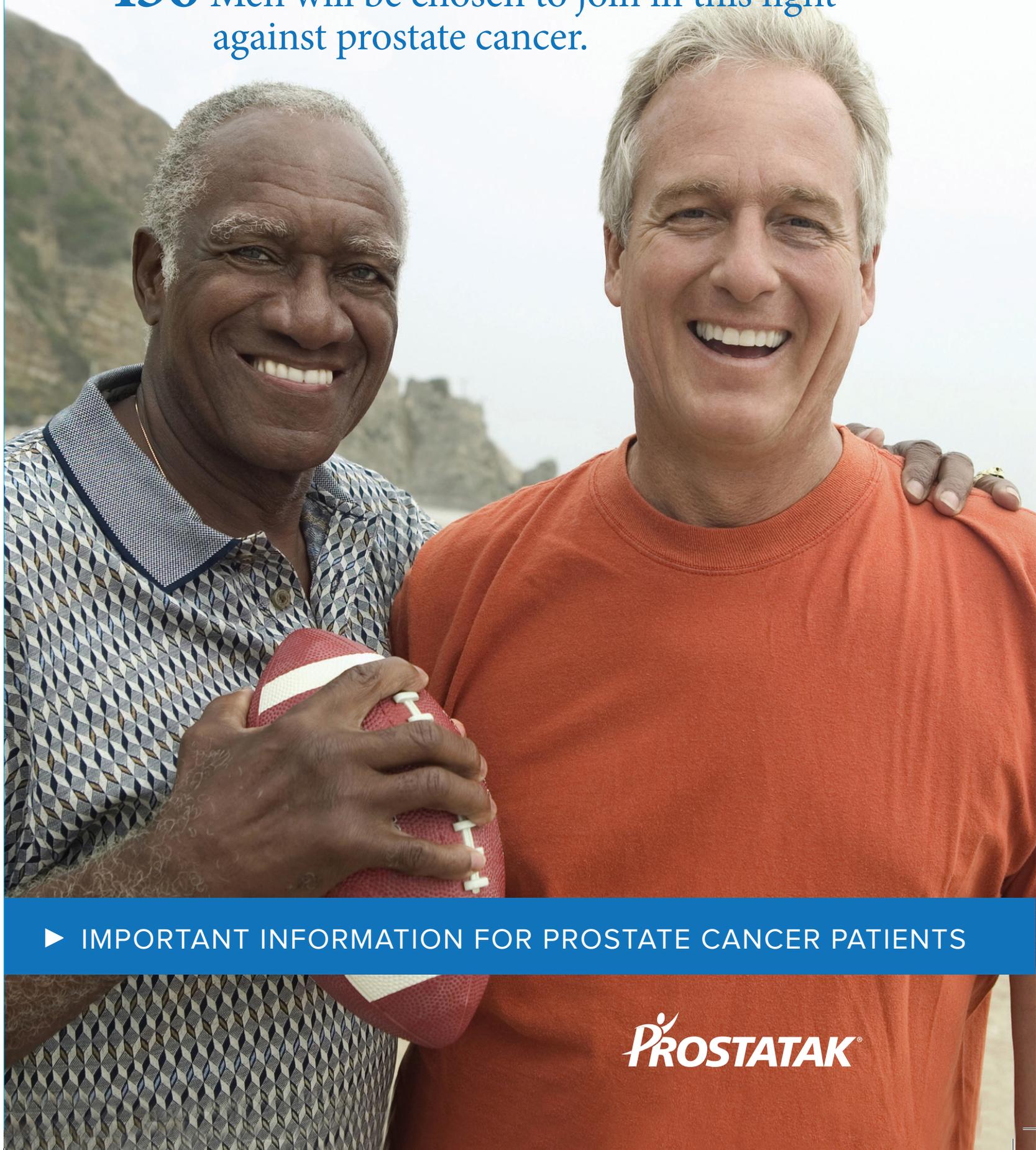


## THE ULYSSES TRIAL

**156** Men will be chosen to join in this fight against prostate cancer.



▶ IMPORTANT INFORMATION FOR PROSTATE CANCER PATIENTS

**PROSTATAK**<sup>®</sup>

**IF YOU HAVE LOCALIZED PROSTATE CANCER, THERE IS EVERY REASON TO BE OPTIMISTIC.**

Thanks to early testing, most prostate cancers are now found while still localized to the prostate. These tumors have not spread outside the prostate and may be managed either by active surveillance or radical treatment.

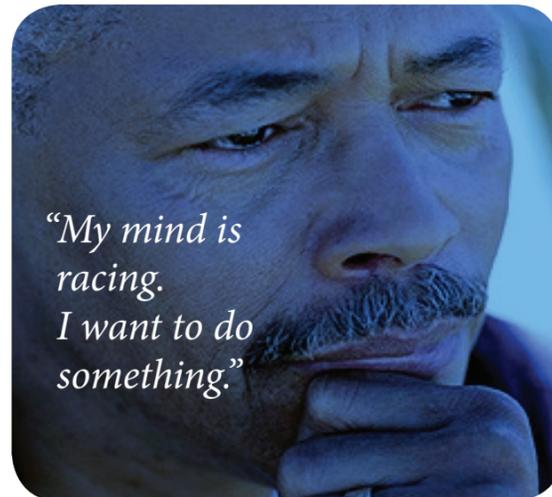
For some patients, the risk from their tumor becoming a major health problem is low, and Active Surveillance (AS), with PSA and biopsy monitoring, is an option. The goal of AS is to avoid overtreatment of slower growing tumors with aggressive treatments that may not be necessary and may have significant side effects.

Radical treatments for localized prostate cancer, such as surgery or radiation, can be curative, but may also have significant short and long-term side effects, including incontinence (urine control problems) and impotence (sexual dysfunction). By choosing Active Surveillance, some patients may avoid or delay those treatments.

Talk it over with your doctor and decide on your best course of action.

**IMMUNOTHERAPY-A FUTURE WEAPON AGAINST PROSTATE CANCER.**

Today, medical research is exploring new ways to use the immune system to treat cancer and to prevent it from progressing to more advanced stages. Prostatak® is an experimental approach that has shown promising results in previous prostate cancer trials. In this study, it is being evaluated to see if when added to Active Surveillance it can prevent progression to avoid or delay the need for surgery or radiation. We call this “**Proactive Surveillance™**.”



**THIS IS WHERE YOU COME IN!**

If you have prostate cancer and choose Active Surveillance, you may qualify to be one of 156 men selected to help in this fight against prostate cancer.

**ARE THERE ANY RISKS?**

You may experience certain side effects as a result of the experimental treatment. In past studies, these side effects have been mostly temporary flu-like symptoms. Your doctor will carefully explain potential risks to you. As with any procedure or treatment, experimental or otherwise, there also may be other side effects or risks that cannot be predicted. There is one other thing to remember: this is a study and needs to be rigorously controlled. To ensure reliability of results and avoid the possibility of bias, it is designed as a “randomized,” double blind, and placebo-controlled study. This means that each participant is randomly selected to receive either Prostatak or a placebo (a harmless liquid). Selection is random, and neither you, nor your doctor nor the sponsor will know to which group you have been assigned.

If you are able to participate, you will receive the same care that you would otherwise. But it’s important to understand that you may spend time, undergo injections and biopsy procedures, and incur side effects, all without aiding the treatment of your disease.

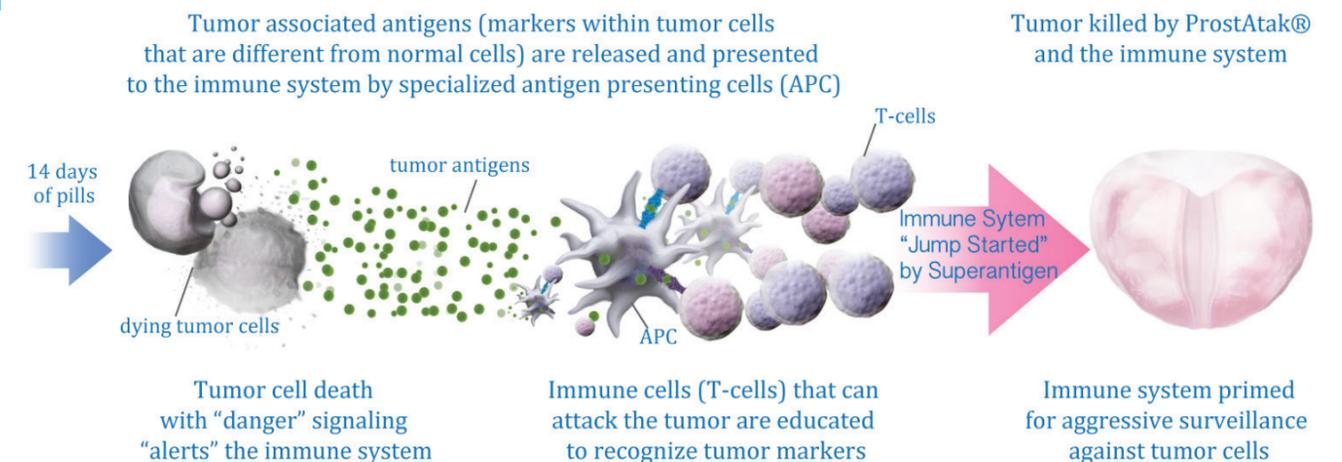
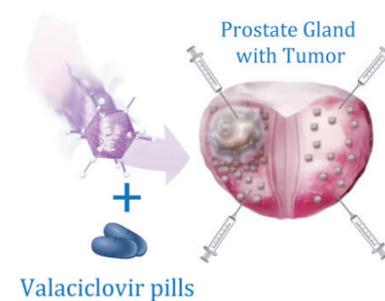
However, all participants will receive the careful evaluations of the protocol and all the care they would have received if they did not participate in the trial-plus a two-to-one chance of receiving Prostatak.



**How Prostatak® Works:**

ProstAtak is part of an innovative approach to cancer treatment called immuno-oncology. It is intended to jump-start the body’s own immune system so it can better detect and destroy cancer cells. This experimental immunotherapy approach is being tested along with Active Surveillance for prostate cancer.

**ProstAtak® injections (4 locations)**



## WHAT'S INVOLVED IN THE STUDY?

Your doctor will explain the full details. In general, the study consists of three parts

### EXPERIMENTAL TREATMENT PHASE

You will receive two courses of the experimental treatment. Each course involves the injection of a dose of either ProstAtak or placebo, followed by 14 days of valacyclovir pills. The injections are performed using transrectal-guided ultrasound (TRUS), the same procedure used to perform a prostate biopsy but with a much thinner needle and no tissue is cut from the prostate. This procedure requires only a few minutes.

### FOLLOW-UP PHASE

After the injections are completed, you will be closely monitored at intervals of 3, 6, 9 and 12 months. These visits will include normal physical exams, blood work to check your PSA and a Quality of Life Questionnaire. A prostate biopsy to evaluate your tumor will be performed at 12 months. These evaluations would likely be performed as standard of care, even if you did not participate in this study.

### LONG-TERM FOLLOW-UP PHASE

After you have completed the 12-month follow-up, you will follow the standard Active Surveillance care, which includes evaluations every 6-12 months.

## WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATING?

There is scientific evidence to believe ProstAtak may improve clinical outcomes during Active Surveillance, but it may not. However, either way, by participating in this study, you will be helping future generations and patients with prostate cancer.

Only you can decide if the potential benefits from participating are worth the possible risks and inconvenience of taking part in this study.

## ARE THERE ANY EXTRA COSTS?

No. You or your insurance will be charged for costs of routine care, such as PSA and biopsies, but you will not be charged for the research components of this study.

## CAN I PARTICIPATE?

If you are interested in taking part in this study or you would like additional information, please speak to your doctor. If the Ulysses trial is still enrolling, you might be eligible to be one of 156 men selected to help in this fight to defeat prostate cancer. Ask your doctor about the possibility of joining.

We know a prostate cancer diagnosis is scary and not doing anything can be frustrating. We are looking to change that. **And we're looking for 156 men who want to help.**