

We want to keep prostate cancer from coming back. We're looking for **711 men who want to help.**

▶ IMPORTANT INFORMATION FOR PROSTATE CANCER PATIENTS

The odds are already in your favor.

If you have been diagnosed with early or intermediate stage prostate cancer, there is every reason to be optimistic.

Thanks to early testing, most prostate cancers are now found before symptoms appear, and treatment by radiotherapy or surgery will, in the majority of cases, lead to a cure.

Sometimes, however, the cancer comes back, even years after the initial treatment. This is called recurrence and it happens in about 30% of patients. At that point it may have spread beyond the prostate; treatment includes medical castration with hormones and chemotherapy, and the risk of treatment failure is considerably higher than before.

A FUTURE WEAPON AGAINST PROSTATE CANCER RECURRENCE?

Today, doctors have a better understanding of cancer than ever before, and medical research is exploring new ways to prevent recurrence. For prostate cancer, a new drug candidate

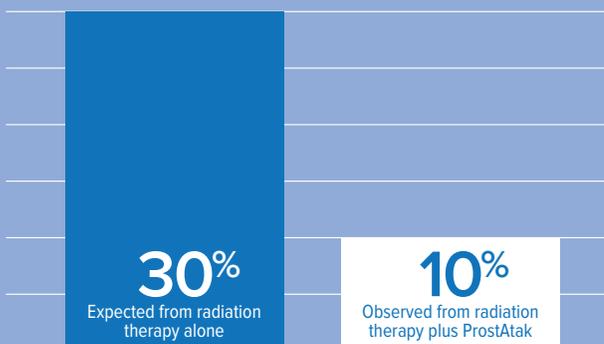
How ProstAtak™ Works:

ProstAtak jump-starts the body's own immune system to detect and destroy recurring cancer cells.

The treatment is done together with standard radiation therapy.

called ProstAtak™ has proven to be especially promising in early trials. In a Phase II study, the rate of recurrence was reduced from an expected 30% down to 10%.

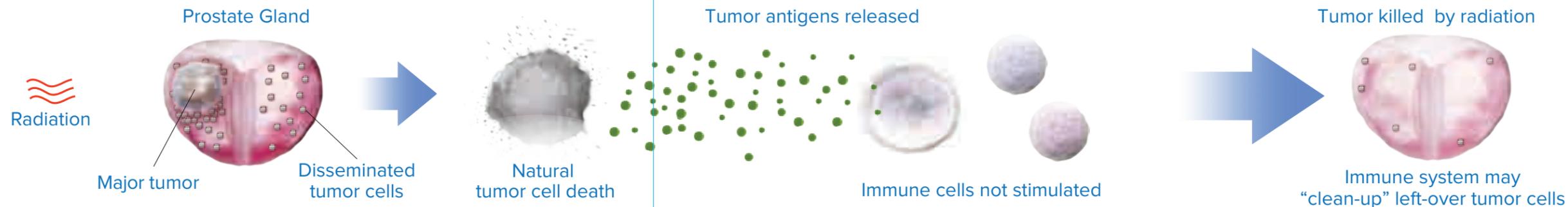
The ProstAtak treatment works something like a vaccine. Based on an innovative technique known as gene transfer technology, it is used in conjunction with standard radiation therapy. The idea, basically, is to “jump-start” the body's own immune system so it can detect and destroy remaining or recurring cancer cells. ProstAtak is not the only cancer vaccine, but at present it is



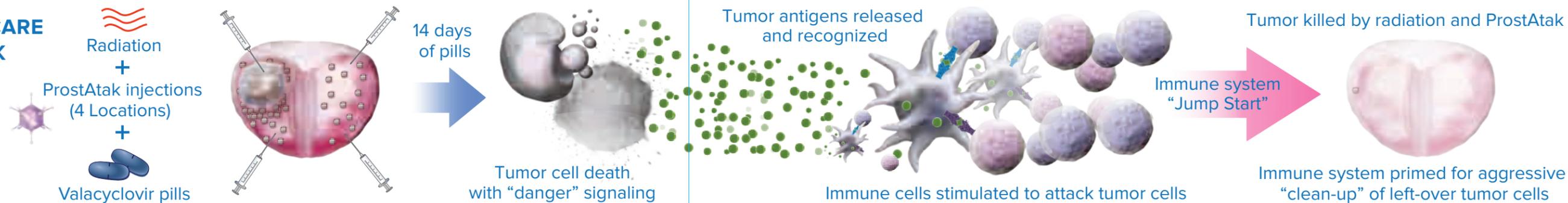
REDUCES PROSTATE CANCER RECURRENCE

In a Phase II clinical trial of ProstAtak given with radiation, prostate cancer recurrence was three-fold lower than typically seen with radiation alone.

STANDARD OF CARE



STANDARD OF CARE + PROSTATAK



the only vaccine product in development for preventing recurrence in newly diagnosed, localized prostate cancers. Like yours.

While the typical drug approval process can take many years, even decades, Prostatak is already in its final stage of evaluation. Early test data on Prostatak have been strong enough to merit so-called "Fast-Track" designation and special FDA approval for an accelerated Phase III clinical trial.

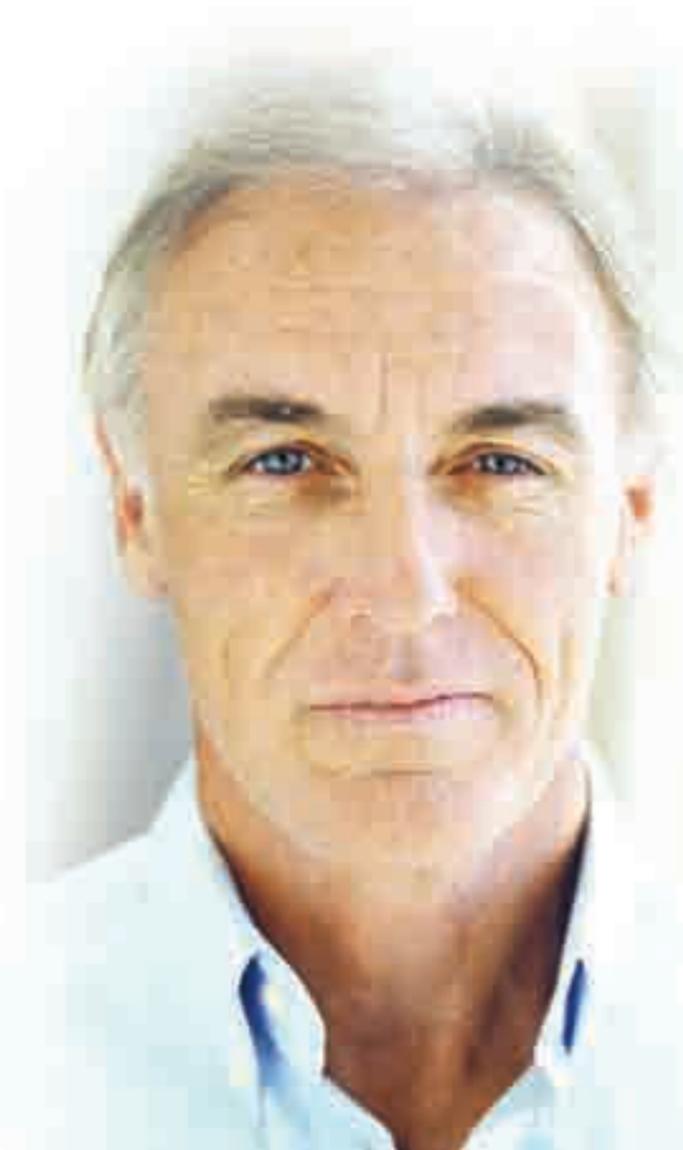
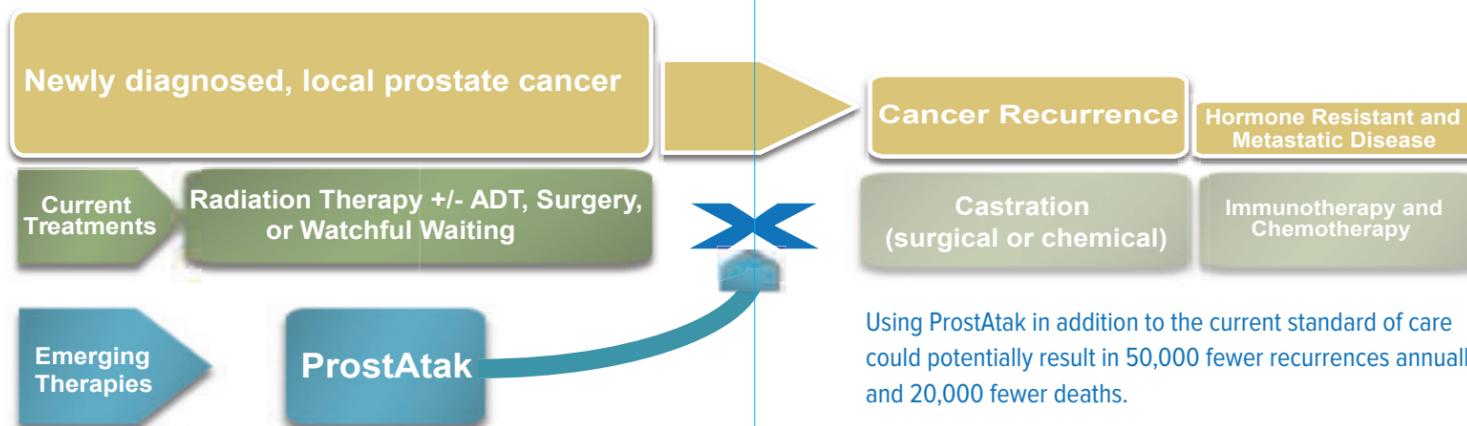
If the outcome of this study is positive, Prostatak is likely to be approved—the first drug ever with early stage prostate cancer as its primary indication.

We're ready to get going. Now the only obstacle to completing this potentially life-saving study is finding qualified patients to participate.

THIS IS WHERE YOU COME IN.

Because you have prostate cancer, you may qualify to take part in this research study. Your doctor will discuss the details of the experimental treatment, which is done in addition to and together with your standard radiation therapy. **It is important to remember that if you participate, you will receive the same standard of care treatment as you would if you do not participate. The only difference is the addition of the study drug being evaluated to prevent cancer recurrence.**

There's one other thing to remember: Because of the way a Phase III trial is set up, **not all participants will receive Prostatak.** Everybody will receive the standard radiation therapy and two out of three men in this study will receive Prostatak; the other one-third will receive a placebo in addition to radiation therapy. Selection is random, and neither you, nor your doctor nor the sponsor of the study will know whether you are receiving Prostatak or the placebo. If you are able to participate, you will receive the same care as otherwise—plus, there is a two-to-one chance you *will* be receiving Prostatak.



WHAT'S INVOLVED IN THE STUDY?

Your doctor will give you complete details of the study, which basically consists of three phases:

1 TREATMENT

You will receive three 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 method used to perform a prostate biopsy. The needle, however, is much thinner, and no tissue is cut from the prostate. The procedure requires only a few minutes.

2 FOLLOW-UP

Following the completion of radiation therapy, you will be monitored at intervals of 3, 6, 12, 18 and 24 months. These visits will include normal physical exams and routine blood work, including checking your PSA. (These evaluations would be performed as standard of care, even if you did not participate in this study.) Approximately two years after radiation therapy, you will undergo a prostate biopsy to help evaluate the effect of ProstAtak and standard of care treatments on your prostate cancer.

3 LONG-TERM FOLLOW-UP

After the two-year biopsy, you will be evaluated every six months for the next three years, and then yearly to assess the long-term effects of your treatments and for general health status. Yearly evaluations for prostate cancer are standard of care, and include both a PSA blood test and physical exam.

What is a Phase III clinical trial?

As you may know, it's not easy for a new drug to reach the market. The Food & Drug Administration (FDA) requires pharmaceutical manufacturers to undertake rigorous, closely-supervised testing to conclusively demonstrate both the safety and efficacy of any new therapy before a drug is approved for widespread use. These tests are called clinical trials, and are conducted in three phases: Phase I tests a new potential drug or treatment in a small group of patients for safety. Phase II involves a larger test group of similar subjects. If these first two are successful, Phase III expands the studies to an even larger group of people, and if the drug successfully passes it is usually approved.

To ensure reliability of results and avoid the possibility of bias in assessing the treatment's effectiveness, many Phase III drug trials are designed as "randomized," double blind, and placebo-controlled. This means that each participant is randomly selected to receive either the study treatment or a placebo (a harmless, inactive pill, liquid, or powder that has no therapeutic value). To avoid potential for bias during the study, neither the subject nor the administering physicians know which treatment each subject is receiving. While a new treatment approach is being tested in a study like the one you are being offered, no aspect of care is excluded—all participants receive the same standard of care as a patient who is not participating in the study.

ARE THERE ANY EXTRA COSTS?

No. You or your insurance will be charged for standard of care costs, such as the radiation, but you will not be charged for the research components of this study that are not covered by third-party payers, such as your insurance or Medicare.

ARE THERE ANY RISKS?

You may experience certain side effects as a result of the experimental treatment. These are usually not serious, and your doctor will carefully explain them to you. In earlier trials, involving approximately 150 patients, ProstAtak has been very well tolerated. As with any course of treatment, experimental or otherwise, there also may be other side effects or risks that cannot be predicted.

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.

While there is reason to believe that the experimental protocol may be effective—ProstAtak would not have been granted Fast-Track status if previous studies had not demonstrated its potential efficacy—there is no guarantee. Your participation may or may not enhance the effects of your radiation therapy.

WHAT ARE THE POSSIBLE BENEFITS?

There is sufficient scientific evidence to believe that ProstAtak may help reduce the risk of your cancer coming back several years down the road, but we do not know for sure.

One thing is certain: Whether you directly benefit from the drug or not, by participating in this study you will be making an important and meaningful contribution towards conquering the disease.

YOU MAY BE IMPROVING THE FUTURE OF PROSTATE CANCER CARE.

Only you can decide. But if you think the potential benefits are worth the possible risks and inconvenience of taking part in this study, you are invited to join the team of 711 men in the fight to defeat prostate cancer.

HOW DO I PARTICIPATE?

If you are interested in taking part in this study, or if you would like additional information, **please speak with your doctor.**