

## **PROVENGE/SIPULEUCEL-T**

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Disclaimer: Please recognize that I am not a Medical Doctor. I have been an avid student researching and studying prostate cancer as a survivor and continuing patient since 1992. I have dedicated my retirement years to continued research and study in order to serve as an advocate for prostate cancer awareness, and, from a activist patient's viewpoint, to help patients, caregivers, and others interested develop an understanding of prostate cancer, its treatment options, and the treatment of the side effects that often accompany treatment. Readers of this paper must understand that the comments or recommendations I make are not intended to be the procedure to blindly follow; rather, they are to be reviewed as my opinion, then used for further personal research, study, and subsequent discussion with the medical professional/physician providing prostate cancer care.

Provenge/sipuleucel-T is a medication designed to enhance activity of the immune system with the intent that with this enhancement, the immune system will be more able to counteract illness factors, as well as enhance the activity and effectiveness of medications prescribed to attack those illnesses...in our case, prostate cancer.

Supportive information for sipuleucel-T/Provenge:

This recent discussion (February 2015) provides likely the best over-view of the activity of Provenge and should encourage physicians who have avoided prescribing this immune boosting procedure to reconsider:

[DT Hot Points 02-19-15 Charles Drake Provenge.pdf](#)

Open the following, enter “Provenge” in the search box, and review articles that regard sipuleucel-T:

<http://www.onclive.com/specialty/prostate-cancer>

It is noted in these articles that though it has been difficult to find markers that identify that sipuleucel-T has activated the immune system, more recent studies of the prostate gland by administering sipuleucel-T prior to surgical removal of the

gland, then reviewing the removed gland following removal, showed immune system activity.

According to study results presented at the 2012 Genitourinary Cancers Symposium, the study explored the possibility of using the vaccine earlier in the treatment timeline than its current approved indication for patients with asymptomatic or minimally symptomatic metastatic castration resistant prostate cancer.

In a phase II trial, 42 patients with localized prostate cancer who were slated for radical prostatectomy were given sipuleucel-T in three infusions administered 6 to 7 weeks prior to their surgeries. Prostate cell specimens were collected prior to and following treatment with sipuleucel-T. Patients were followed for 72 weeks, and also randomly assigned to receive a booster treatment with the vaccine or no further treatment.

At the time of the presentation in February 2012, immunohistochemistry analysis had been completed on 19 patients. “Significant increases (>2-fold) in CD3-positive and CD4-positive T-cell populations were observed at the tumor rim, where benign and malignant glands interface, compared with the pretreatment biopsy,” researchers said in their abstract. Surgical impact was measured by operative complications, procedure time, and estimated blood loss.

In a companion abstract, investigators reported a “robust immune system activation,” including antigen-presenting cells and memory and activated mature B cells.

An explanation of the action of Provenge is explained in the URL below where you can scroll down to “Mechanism of Action”.

<http://www.drugs.com/pro/provenge.html>

In a presentation at the 17th European Cancer Congress (ECCO), Tomasz Beer, M.D., FACP of the Oregon Health & Science University Knight Cancer Institute, a specialist in research and treatment with Provenge/sipuleucel-T, reported that in a study administering a second round of Provenge to seven men at an average 9.2 years following their initial treatment, and wherein they did several forms of diagnostics to determine activity, they determined that the effects on the immune system from the initial treatment were still in evidence this 9.2 years later. Then,

following this second round of administration, diagnostics provided evidence that there were significant uptakes indicating the medication appeared to be even more effective than the initial treatment.

More often than not, after having been prescribed Provenge, we see little change in PSA activity. This is not a medication expected to immediately bring down elevating PSA. It appears from all I have researched and read that Provenge appears to be more effective the earlier prescribed while the PSA level is still relatively low and prior to the cancer having become more aggressive in development. At the time of this writing, Provenge/sipuleucel-T is approved for prescribing following apparent failure of androgen deprivation therapy and then only if the patient is experiencing metastasis, either symptomatic or asymptomatic. It would appear to me that rather than waiting for metastases to occur, this would be the most appropriate time for prescribing this medication for a more effective enhancement of the immune system to hopefully even prevent or significantly slow down development before the cancer becomes metastatic.

For awareness, the following from [www.provenge.com](http://www.provenge.com) regarding possible side effects:

“PROVENGE can cause serious reactions. In controlled clinical trials for the treatment of prostate cancer, serious reactions reported in patients in the PROVENGE group include reactions resulting from the infusion of the drug, which occurred within 1 day of infusion, and strokes. Severe infusion reactions included chills, fever, fatigue, weakness, breathing problems (shortness of breath, decreased oxygen level, and wheezing), dizziness, headache, high blood pressure, muscle ache, nausea, and vomiting. Tell your doctor right away if you have breathing problems, chest pains, racing heart or irregular heartbeats, dizziness, nausea, or vomiting after getting PROVENGE **because any of these may be signs of heart or lung problems.** (I high-lighted the last for emphasis).

The most common side effects reported with PROVENGE are chills, fatigue, fever, back pain, nausea, joint ache, and headache. These are not all the possible side effects of PROVENGE treatment. For more information, talk with your doctor.”