



It's Worth the Fight: Advanced Prostate Cancer

Background – Advanced Prostate Cancer

For men, few health conditions are as common as prostate cancer, a disease that affects nearly one in every six men in the United States.^{1A} More than 240,000 American men are expected to be diagnosed with prostate cancer in 2011.^{1F} Other than skin cancer, prostate cancer is the most common cancer and the second-leading cause of cancer-related death in American men.^{1C} Prostate cancer causes more than 33,000 deaths annually in the U.S.^{1D} Roughly one of every 36 men in this country will die from prostate cancer;^{1J} only lung cancer surpasses this rate.^{1C}

As with many diseases, prostate cancer can be particularly troublesome in its advanced stages. Although early-stage prostate cancer usually causes no symptoms^{1G}, an estimated 15 percent of cases are not discovered until the disease has advanced or become metastatic (i.e., spread to lymph nodes or other body parts beyond the prostate).^{2A} Symptoms of advanced prostate cancer include urinary problems such as a slow or weakened urinary stream, or a frequent need to urinate.^{1T} A man with advanced prostate cancer may also experience hematuria (blood in the urine) or impotence (difficulty having an erection). Additionally, advanced prostate cancer often spreads to the bones, causing pain in the hips, back, chest, or other areas. Cancer that has metastasized to the spine may also press on the spinal nerves, resulting in weakness or numbness in the legs or feet, or in some cases, loss of bladder or bowel control.^{1H}

Veterans and Prostate Cancer

Notably, almost two of every three cases of prostate cancer occur in men older than 65 years^{1E}, making this disease a health issue of particular relevance to veterans, who are either a part of or will soon enter this age group. In particular, veterans who served in the Vietnam war who were exposed to the herbicide Agent Orange are at greater overall risk of prostate cancer.^{4A} In a study of more than 13,000 Vietnam veterans, published in 2008, the authors concluded that those who were exposed to Agent Orange have a increased risk of prostate cancer,^{4B} and a substantial increased risk of metastatic prostate cancer, compared to those who were not exposed.^{4C}

It's Worth the Fight

It's Worth the Fight is a program designed to shine a light on the special needs of men with advanced prostate cancer. While the program specifically targets veterans, it is relevant for all men at risk of or living with prostate cancer. Supported by Sanofi in collaboration with Men's Health Network (MHN), Women Against Prostate Cancer (WAPC), and the Veterans Health Council (VHC), the campaign calls upon men (along with the women and family members in their lives) to summon their resolve to help themselves fight this disease.

The It's Worth the Fight program kicked off in October with a live event at the Washington DC Veterans Affairs Medical Center, and featured presentations by representatives of MHN, WAPC, and VHC. The live event was followed up with a webcast on Veterans Day, November 11, 2011.



A major focus of the It's Worth the Fight program is the "three C's" of advanced prostate cancer, which encourage men to take a more active role in their health and in managing their disease. Specifically, the three C's urge men with advanced prostate cancer to:

- Communicate as your prostate cancer advances:
 - You're not alone – there are steps you can take to cope with advanced prostate cancer.
 - Be proactive and talk to your family. Use your family as a resource to educate yourself about the disease and your options.
- Consult a team of health professionals:
 - Working with a multidisciplinary team (MDT) of experts, you can help improve treatment outcomes.⁶
 - The core MDT typically consists of the patient's urologist, medical oncologist, and radiation oncologist. Oncology nurses, pain specialists, nutritionists, psychologists, and social workers are also important members of the MDT, and are called upon as needed.
- Consider your options:
 - There are several treatment options available to you, even if your prostate cancer is in the advanced stages.
 - In recent years there have been significant advances in the treatment of advanced prostate cancer. Be sure to ask your healthcare team what treatments are available and consider ALL of your options.

Recent Treatment Advances for Advanced Prostate Cancer

Men with advanced prostate cancer may potentially benefit from immunotherapy, which is also known as cancer vaccine treatment. Immunotherapy works by boosting the body's immune response to prostate cancer cells.¹¹ Provenge (sipuleucel-T) is a recently introduced immunotherapeutic agent that uses the patient's own cells to boost his immune system to fight prostate cancer. It is indicated for treatment of asymptomatic or minimally symptomatic hormone refractory metastatic prostate cancer (mHRPC).¹⁰

Another type of treatment is hormone therapy, which involves the use of drugs, surgery, or other hormones to remove the male sex hormones or block their effects, thereby preventing cancer cells from growing.^{7A} Abiraterone acetate (Zytiga) is a hormone therapy that inhibits an enzyme expressed in testicular, adrenal, and prostatic tumor tissues and is required for androgen biosynthesis.¹⁰ It is indicated in combination with prednisone for treatment of patients with mHRMPC previously treated with docetaxel.¹¹

One medication, Xgeva (denosumab), impacts a cellular receptor responsible for bone formation. It is indicated for prevention of skeletal-related events (e.g., broken bones, surgery to repair broken bones, radiation to relieve bone pain, or pressure on the spinal cord)¹³ in patients with bone metastases from solid tumors.¹³



Chemotherapy is a treatment option that represents the use of drugs to shrink or kill cancer.^{7B} Chemotherapy works by traveling through the body and attacking cells that divide quickly, such as cancer cells.^{1W} In so doing, chemotherapy may delay the growth of cancer or alleviate symptoms.^{1Y} Jevtana® (cabazitaxel) Injection is a chemotherapeutic agent that disrupts the skeleton of the cell when it divides.^{9B} It is indicated in combination with the steroid medication prednisone for treatment of patients with hormone refractory metastatic prostate cancer (mHRMPC) previously treated with a docetaxel-containing treatment regimen.^{9A}

IMPORTANT SAFETY INFORMATION FOR JEVTANA (CABAZITAXEL) INJECTION

WARNING

- **Neutropenic deaths have been reported. In order to monitor the occurrence of neutropenia, frequent blood cell counts should be performed on all patients receiving JEVTANA®. JEVTANA® should not be given to patients with neutrophil counts of $\leq 1,500$ cells/mm³**
- **Severe hypersensitivity reactions can occur and may include generalized rash/erythema, hypotension and bronchospasm. Severe hypersensitivity reactions require immediate discontinuation of the JEVTANA® infusion and administration of appropriate therapy. Patients should receive premedication**
- **JEVTANA® must not be given to patients who have a history of severe hypersensitivity reactions to JEVTANA® or to other drugs formulated with polysorbate 80**

CONTRAINDICATIONS

- JEVTANA® should not be used in patients with neutrophil counts of $\leq 1,500$ /mm³
- JEVTANA® is contraindicated in patients who have a history of severe hypersensitivity reactions to JEVTANA® or to other drugs formulated with polysorbate 80

WARNINGS AND PRECAUTIONS

- Neutropenic deaths have been reported
 - Monitoring of complete blood counts is essential on a weekly basis during cycle 1 and before each treatment cycle thereafter so that the dose can be adjusted, if needed
 - Monitor blood counts frequently to determine if initiation of G-CSF and/or dosage modification is needed
 - Primary prophylaxis with G-CSF should be considered in patients with high-risk clinical features
- Severe hypersensitivity reactions can occur
 - Premedicate with corticosteroids and H₂ antagonists
 - Patients should be observed closely for hypersensitivity reactions, especially during the first and second infusions
 - Discontinue infusion immediately if hypersensitivity is observed and treat as indicated
- Mortality related to diarrhea has been reported
 - Rehydrate and treat with anti-emetics and anti-diarrheals as needed
 - If experiencing grade ≥ 3 diarrhea, dosage should be modified

Please see the additional Important Safety Information on the next page and accompanying full prescribing information, including boxed **WARNING**



IMPORTANT SAFETY INFORMATION FOR JEVTANA (CABAZITAXEL) INJECTION (Continued)

WARNINGS AND PRECAUTIONS (Continued)

- Nausea, vomiting and severe diarrhea, at times, may occur. Death related to diarrhea and electrolyte imbalance occurred in the randomized clinical trial. Intensive measures may be required for severe diarrhea and electrolyte imbalance.
- Renal failure, including cases with fatal outcomes, has been reported. Identify cause and manage aggressively
- Patients ≥ 65 years of age were more likely to experience fatal outcomes not related to disease progression and certain adverse reactions, including neutropenia and febrile neutropenia. Monitor closely
- Patients with impaired hepatic function were excluded from the randomized clinical trial
 - Hepatic impairment is likely to increase the JEVTANA[®] concentrations
 - JEVTANA[®] should not be given to patients with hepatic impairment
- JEVTANA[®] can cause fetal harm when administered to a pregnant woman
 - There are no adequate and well-controlled studies in pregnant women using JEVTANA[®]
 - Women of childbearing potential should be advised to avoid becoming pregnant during treatment with JEVTANA

ADVERSE REACTIONS

- Deaths due to causes other than disease progression within 30 days of last study drug dose were reported in 18 (5%) JEVTANA[®]-treated patients. The most common fatal adverse reactions in JEVTANA[®]-treated patients were infections (n=5) and renal failure (n=4)
- The most common ($\geq 10\%$) grade 1–4 adverse reactions were anemia, leukopenia, neutropenia, thrombocytopenia, diarrhea, fatigue, nausea, vomiting, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysgeusia, cough, arthralgia, and alopecia
- The most common ($\geq 5\%$) grade 3–4 adverse reactions in patients who received JEVTANA[®] were neutropenia, leukopenia, anemia, febrile neutropenia, diarrhea, fatigue, and asthenia

Please see the accompanying full prescribing information for Jevtana, including boxed **WARNING**, or visit <http://products.sanofi-aventis.us/jevtana/jevtana.pdf>

Summary

Although medication is a vital component of managing advanced prostate cancer, it is not the only component: communication is at least as important. For men with advanced prostate cancer to manage their disease effectively, they must communicate not only with their health care providers, but also with their families, who serve as a vital source of support. It is also important for men with advanced prostate cancer to consult an MDT of health professionals, an approach that has been shown to help improve treatment outcomes. The MDT can help prostate cancer patients consider all available treatment options, while also counseling them on proper diet, exercise, and other issues.

For many men with advanced prostate cancer, managing the disease may be the most daunting challenge of their lives, one that requires an inner resolve not unlike a warrior's fighting spirit. Fortunately, there are a host of people and resources to help men summon the resolve to fight prostate cancer. It is that inner resolve that the It's Worth the Fight program seeks to recognize, celebrate, and encourage.



References

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