

# **ACTIVATE YOUR IMMUNE SYSTEM** TO FIGHT ADVANCED PROSTATE CANCER WITH **PROVENGE**



PROVENGE has been proven to help certain men with advanced prostate cancer live longer.



# PROVENGE (sipuleucel-T)

### What is **PROVENGE**?

PROVENGE is the first FDA-approved personalized immunotherapy that is clinically proven to extend the life of certain men with metastatic castration-resistant prostate cancer (mCRPC). Men are diagnosed with mCRPC when their cancer has spread (metastasized) to other areas of the body and the cancer becomes resistant to androgen deprivation therapy (ADT).



# What is immunotherapy?

The immune system is made of a variety of cells working together as the body's defense against foreign substances, such as disease and cancer. One of the natural abilities of the immune system is to detect abnormal cells, including cancer cells, and destroy or prevent them from spreading. In some cases, cancer may overwhelm or hide from the immune system and may spread to other areas of the body.

Immunotherapy is the prevention or treatment of disease with substances that may stimulate an immune response.

# Why **PROVENGE**?

PROVENGE is personalized, using your own immune system. Unlike traditional prostate cancer therapies, such as chemotherapy or hormone therapy, PROVENGE works differently.

The immune system has memory and can recognize substances it encountered previously. PROVENGE immunotherapy is designed to boost the immune system to target and attack prostate cancer cells. This is why PROVENGE empowers the immune system to fight the cancer immediately and allow the effects to last over time.

The most common side effects of PROVENGE are generally mild to moderate and well tolerated.

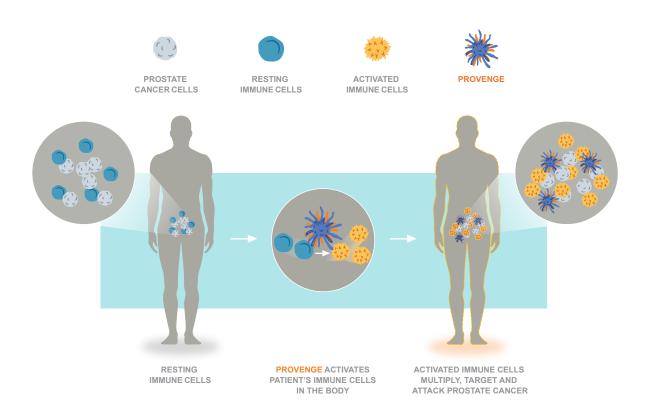
The PROVENGE treatment process can be completed in 6 appointments throughout the course of about a month.

SINCE FDA APPROVAL IN 2010



### How **PROVENGE** Works

PROVENGE activates your resting immune cells, which then replicate, target and attack prostate cancer cells.



#### Is **PROVENGE** for me?

PROVENGE immunotherapy is indicated for men with mCRPC that:

- Have disease progression while on androgen deprivation therapy (ADT)
- Have been diagnosed with metastatic disease, meaning the cancer has spread from the prostate to other areas, such as bones or lymph nodes
- Are not taking narcotics for cancer related pain

Please see the back of this brochure for additional Important Safety Information

Or visit www.PROVENGE.com

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# WHAT TO EXPECT WITH PROVENGE

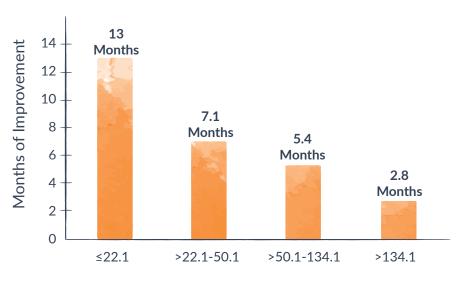
PROVENGE extends life for certain men with metastatic CRPC.

Data from an exploratory analysis of the pivotal phase III trial (IMPACT) suggests that men who received PROVENGE with a PSA ≤22.1 ng/mL when they started treatment, saw improved median overall survival of over 1 year.\*



In all quartiles of the exploratory analysis, men who received PROVENGE saw improved median overall survival when compared to men who did not receive PROVENGE (Control).

## Improvement to Median Overall Survival



Baseline PSA Quartiles (ng/mL)

\*Individual results may vary.

# THE MOST COMMON SIDE EFFECTS OF **PROVENGE** ARE GENERALLY MILD TO MODERATE AND WELL TOLERATED

Serious adverse events have occurred in some men who received PROVENGE. Tell your doctor right away if you experience any side-effects.



## 95% of infusion-related side effects were mild to moderate

In controlled clinical trials, 71.2% of men who received PROVENGE developed an acute infusion reaction, most of which were mild to moderate. They included fevers and chills, which were typically resolved within 2 days (71.9% and 89%, respectively).

The most common side effects of PROVENGE are:

- ChillsFeverNauseaHeadacheFatigueBack painJoint ache
- 1.5% of men in the pivotal trial discontinued their treatment due to side effects.

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# **PROVENGE** treatment can be completed in about a month

The PROVENGE treatment process includes 3 personalized cycles using your own immune cells, activating them to empower your immune system. This process can be completed in 6 appointments throughout the course of about a month.



#### **PROVENGE** Treatment Process

#### **Step 1: Cell Collection**

• Treatment begins at your local blood bank with leukapheresis, a 2-4 hour process where blood is drawn into a machine. The machine extracts a small amount of your immune cells, along with some platelets and red blood cells. The remainder of the blood is returned back during the process.

The collected immune cells are sent to a state-of-the-art facility and made into PROVENGE.

#### **Step 2: PROVENGE Infusion**

• Approximately 3 days after cell collection, PROVENGE is administered through an intravenous (IV) infusion, which takes about 1 hour.

A Patient Care Kit will be provided prior to receiving PROVENGE. The kit outlines helpful reminders throughout the entire process. It is important to keep your scheduled appointments in order to prevent delays in completing your treatment.

# Support and Coverage

Men living with advanced prostate cancer may find it difficult to ask for help. Find support organizations, locate urologists or oncologists, and connect with men that have advanced prostate cancer by visiting www.PROVENGE.com/Support.

PROVENGE is covered by Medicare as well as most commercial plans. For men receiving PROVENGE, 90% of Medicare Fee-For-Service (FFS) members are expected to have minimal to no out-of-pocket costs, and 85% of out-of-pocket costs are less than \$50.

Travel assistance programs may be available to those that qualify. Visit www.PROVENGE.com/Support to learn more.

# Think more about special occasions.

Think **less** about **cancer**. Start **PROVENGE** today!



# NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®)

The National Comprehensive Cancer Network® (NCCN®) is an alliance of 28 leading cancer centers devoted to patient care, research, and education. NCCN recommends considering sipuleucel-T (PROVENGE) as an initial treatment option for certain men with mCRPC. NCCN also recommends sipuleucel-T (PROVENGE) as a treatment option even if you have received other treatments for advanced prostate cancer.



Sipuleucel-T (PROVENGE) should be considered as an initial treatment option for certain men with mCRPC.

\*Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2019. ©National Comprehensive Cancer Network, Inc. 2019. All rights reserved. Accessed October 30, 2019. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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#### **INDICATION**

PROVENGE® (sipuleucel-T) is a prescription medicine used to treat certain men with advanced prostate cancer. PROVENGE is an established cellular immunotherapy and is customized to each individual by using his own immune cells.

#### IMPORTANT SAFETY INFORMATION

Before receiving PROVENGE®, tell your doctor about any medical conditions, including heart or lung problems, or if you have had a stroke.

Tell your doctor about any medicines you take, including prescription and nonprescription drugs, vitamins, or dietary supplements.

The most common side effects of PROVENGE include chills, fatigue, fever, back pain, nausea, joint ache, and headache. These are not all the possible side effects of PROVENGE treatment.

PROVENGE is made from your own immune cells, which are collected during a process called leukapheresis. The cells are processed, returned, and then infused back into the patient through an IV (intravenous) infusion approximately 3 days later. This process is completed in 3 cycles, about 2 weeks apart. Each infusion takes approximately 1 hour and requires 30 minutes of post-infusion monitoring.

PROVENGE infusion can cause serious reactions. Tell your doctor right away if you:

- Have signs of a heart attack or lung problems, such as trouble breathing, chest pains, racing or irregular heartbeats, high or low blood pressure, dizziness, fainting, nausea, or vomiting
- Have signs of a stroke, such as numbness or weakness on one side of the body, decreased vision in one eye, or difficulty speaking
- Develop symptoms of thrombosis which may include: pain and/or swelling of an arm or leg with warmth
  over the affected area, discoloration of an arm or leg, shortness of breath, chest pain that worsens on deep
  breathing
- Have signs of infection such as a fever over 100°F, redness or pain at the infusion or collection sites

Tell your doctor about any side effect(s) that concerns you or does not go away. For more information, talk with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see enclosed full Prescribing Information.

