# THE POWER TO FIGHT ADVANCED PROSTATE CANCER IS ALREADY IN YOU. TURN IT ON.

Learning About Your Treatment for Advanced Prostate Cancer

A prostate cancer cell

An activated immune cell



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www.PROVENGE.com

PROVENGE is the only FDA-approved treatment for certain men with advanced prostate cancer that uses their own immune system to fight the disease.

#### **IMPORTANT INFORMATION FOR PATIENTS**

**INDICATION:** PROVENGE<sup>®</sup> (sipuleucel-T) is approved by the FDA as an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

**IMPORTANT SAFETY INFORMATION:** PROVENGE is made from your own immune cells. Your cells will be collected at a cell collection center approximately 3 days before each scheduled infusion of PROVENGE. There can be risks associated with the cell collection process, which you should discuss with your doctor before deciding to begin treatment with PROVENGE.

PROVENGE can cause serious reactions. In controlled clinical trials for the treatment of prostate cancer, serious reactions reported in patients in the PROVENGE group included 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.

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.

Tell your doctor about all your medical problems, including heart problems, lung problems, or a history of stroke.

Tell your doctor right away if you get a fever over 100°F, or redness at the cell collection or infusion sites, because any of these may be signs of infection.

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

Tell your doctor about any side effect that concerns you or does not go away.

For more information on PROVENGE, please see the accompanying full Prescribing Information or call *Dendreon ON Call* at 1-877-336-3736.

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**PROVENGE** (sipuleucel-T)

### What Is PROVENGE?

PROVENGE (pronounced PROH-venj) is an **autologous** (pronounced aw-tall-oh-gus) **cellular immunotherapy**.



PROVENGE is a treatment option for men with **asymptomatic** or **minimally symptomatic metastatic castrate resistant** (hormone refractory) prostate cancer.



PROVENGE is designed to use your immune system to fight prostate cancer. Your immune system is made up of immune cells found in your blood. These cells work as your body's natural defense against all types of illness, including prostate cancer.

Your personalized dose of PROVENGE consists of your own immune cells that have been activated with a **recombinant antigen** to seek and attack prostate cancer cells. By stimulating the natural ability of immune cells already in your blood, PROVENGE may help you live longer.

### How Is PROVENGE Different?

Even though your immune system works to defend you against infection and disease, sometimes cancer cells can "hide" from your immune system.

# **PROVENGE** is designed to train your body's immune cells to seek and attack prostate cancer cells.



PROVENGE is the only FDA-approved prostate cancer immunotherapy. It is the first in a new class of therapy to use this approach.

*Note:* Important words are introduced with **bold type**. These terms are also listed and defined in the glossary found on page 17.



### What Are the Benefits I Might Receive From PROVENGE?

PROVENGE is an exciting innovation in the treatment of advanced prostate cancer.

- PROVENGE may help you live longer
- In a clinical study, PROVENGE reduced the risk of death in men by 22.5%
- Treatment is complete after 3 **infusions**, given approximately 2 weeks apart
- The most common side effects are primarily mild or moderate
- These side effects include chills, **fatigue**, fever, back pain, nausea, joint ache, and headache

In one study of PROVENGE, less than 1.5% of patients in the PROVENGE group had to stop treatment due to side effects.



The **prostate-specific antigen (PSA)** test is often used to monitor progression of prostate cancer and how effective your treatment may be at controlling it. It is important to note that changes in PSA levels may not be a good sign of whether you are benefitting from treatment with PROVENGE. Even if your PSA levels don't change, PROVENGE may still be working.



Talk to your doctor if you have any questions or concerns about your PSA levels.





### What Important Safety Information Should I Know About PROVENGE?



PROVENGE can also cause serious reactions, including reactions resulting from the infusion itself, which occurred within 1 day of infusion, and strokes.

Severe infusion reactions include chills, fever, fatigue, weakness, breathing problems (shortness of breath, decreased oxygen level, and wheezing), dizziness, headache, high blood pressure, muscle ache, nausea, and vomiting.

These are not all the possible side effects of PROVENGE treatment.

Each dose of PROVENGE is checked several times for quality (which includes a **sterility** test) before your infusion. However, the results from the final test are not typically available before your infusion. This means it's possible that you may receive an infusion that did not pass the final test. If this occurs, your doctor will be contacted immediately to determine how best to treat you.

# Before starting treatment with PROVENGE, tell your doctor about:

- Any medical problems you have, such as heart problems, lung problems, and if you have had a stroke
- All medicines you take, including prescription and over-the-counter medicines, vitamins, and supplements

#### After treatment with PROVENGE, tell your doctor if you:

- Have breathing problems
- Have chest pains
- Feel your heart racing or have an irregular heartbeat
- Feel dizzy
- Feel nauseous or vomit
- Have a fever (a temperature over 100°F)
- Have redness or pain at the infusion or cell collection sites

These may be signs of heart or lung problems or of infection.

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

For more information on PROVENGE, please see the accompanying full Prescribing Information.



### How Are My Cells Collected?

Each dose of PROVENGE is made just for you. To make each dose, blood is drawn and flows through a tube to a machine that collects a small portion of immune cells from the blood sample. This process is called **leukapheresis** (pronounced loo-kuh-fuh-REE-sis).

Before your first leukapheresis procedure, you will need a common blood test called a **complete blood count (CBC)**. This test measures your blood-cell levels.

Your doctor will also check your veins to decide the best way for your blood to be drawn. This may be through a vein or through a **central venous catheter**, a thin, flexible tube placed into a large vein near the heart. If your doctor decides you need a central venous catheter, it will be kept in place for all of your blood draws as well as each of your PROVENGE infusions.

#### Steps of the Leukapheresis Procedure

Your blood will flow from your vein into a machine where it is separated into

different parts

A small portion of your immune cells (along with some of the platelets and a small amount of red blood cells) are removed

### 3

The rest of the cells and the blood are returned to your body

It will take about 3 to 4 hours for the entire leukapheresis procedure. Many patients like to listen to music or watch a movie during this time. Your procedure will take place at a blood center that has been trained to perform the leukapheresis procedure. Some people may notice side effects when their cells are collected. These can include dizziness, fatigue, tingling in the fingers and around the mouth, feeling cold, fainting, and nausea. For more information, talk with your doctor.



#### Before Your Leukapheresis Procedure...

- Make sure to drink more water than usual to stay well hydrated
- Avoid drinking caffeinated beverages on the day of each leukapheresis procedure
- Eat a calcium-rich breakfast, which may include yogurt, milk, calcium-fortified orange juice or cereal, bananas, blueberries, or almonds
- Wear comfortable, loose-fitting clothing, especially clothing with sleeves that can be raised above the elbow
- In general, most people feel fatigued after the leukapheresis procedure, so having an alternate driver for the ride home is recommended



### How Is PROVENGE Given?

PROVENGE is infused 3 times, with infusions given approximately every 2 weeks. Each infusion of PROVENGE is about 3 days after your leukapheresis procedure (*For more information on the leukapheresis procedure, see page 8*). After 3 infusions, your treatment with PROVENGE is complete.





Your doctor's office will work with *Dendreon ON Call* to create a personalized treatment schedule just for you. *Dendreon ON Call* is staffed by a dedicated team of specialists who provide support to your doctor's office throughout your treatment, including scheduling help.

#### A sample schedule is shown below for your reference.





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### How Is PROVENGE Given? (continued)

Once your schedule is confirmed, you will receive a Comfort Kit that will have information about PROVENGE. The Comfort Kit will also include items to make your treatment as comfortable as possible.

It is important to keep all your scheduled appointments and to arrive prepared. Your dose of PROVENGE, once manufactured, has a short life span. If an infusion appointment is missed, your personal dose of PROVENGE will expire and be out of date and can no longer be used. You will have to repeat the leukapheresis procedure in order for a new dose to be manufactured.



If you miss a leukapheresis procedure appointment, or the procedure cannot be performed, then your infusion appointment and all other remaining appointments may need to be rescheduled.

To prevent the need for repeat procedures, set reminders for yourself. You can use the calendar provided in your Comfort Kit, and you can also ask family members or friends to mark these dates on their calendars as well.

#### Things to Remember for Your Appointments

You must bring a government-issued photo ID, such as a driver's license, to all your appointments.

It should have the same name (first, middle or middle initial, and last name) as used for the records at your doctor's office at the time of enrollment for PROVENGE treatment. This will allow the doctor's office to match your dose of PROVENGE to you.



#### Items You May Wish to Bring With You to Pass the Time During Your Infusion Appointment...

Portable music device

Book

Items from your PROVENGE Comfort Kit



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### Overview: PROVENGE Therapy at a Glance

Now that you and your doctor have decided that PROVENGE is the right treatment for you, it is important for you to play an active role in the treatment process. This chart provides you with an overview of the process, so you can fully understand the commitment necessary to complete your full course of therapy.



See the glossary at the end of the brochure for definitions of terms you may be unfamiliar with.



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### What Support Is Available During My Treatment?

Please contact your health care provider if you have any urgent questions about PROVENGE. Listed below are other resources that you might find helpful.

#### **Financial Assistance**

Dendreon, the company that makes PROVENGE, has given grants to independent foundations that provide financial assistance and other support to men with prostate cancer. These foundations may offer:

- Assistance with co-pay, co-insurance, and deductible costs
- Assistance with travel-related treatment costs

In addition, Dendreon sponsors a program that provides PROVENGE, free of cost, to eligible patients with no health insurance.

You can call a toll-free number, 1-877-336-3736, to obtain more information on these financial assistance services.

Chronic Disease Fund www.cdfund.org 1-877-968-7233 Patient Advocate Foundation www.copays.org 1-866-512-3861

Patient Access Network Foundation www.panfoundation.org 1-866-316-7263

**Us TOO** www.ustoo.com 1-800-808-7866

For a listing of additional patient resources, visit www.PROVENGEresources.com.

#### **PROVENGE.com**

The PROVENGE Web site (www.PROVENGE.com) is another helpful resource during your treatment. You can find more information about advanced prostate cancer, how PROVENGE works, videos explaining the treatment process, and additional support resources.

### Glossary

**asymptomatic:** having no symptoms. For men being considered for treatment with PROVENGE, this means having no prostate cancer-related pain and not needing narcotics to lessen cancer-related pain

**autologous:** comes from you. PROVENGE is an autologous treatment because it is made from cells that come from your body

**castrate resistant (hormone refractory) cancer:** cancer that does not respond to hormone treatment or that gets worse while being treated with hormone therapy

 ${\ensuremath{\textbf{cellular}}}$  made of cells. PROVENGE is a cellular treatment because it is made of the man's own cells

**central venous catheter:** a long, thin, flexible tube put into a vein in the arm or chest that goes to a large vein near the heart

complete blood count (CBC): a test that measures the amount of different types of blood cells

fatigue: a feeling of weariness and tiredness

hormone therapy: treatment that decreases the level of hormones in the body

**immunotherapy:** treatment that helps the immune system (the body's natural defense) fight disease

infusion: the act of putting fluid (usually a medication) into a vein

**leukapheresis:** the process of removing some white blood cells from the blood of a patient and returning the rest of the cells to the patient's body

**metastatic:** spread from the original location to other parts of the body; in prostate cancer, cancer that has spread from the prostate to places such as the bones

**minimally symptomatic:** having minor symptoms. For men being considered for treatment with PROVENGE, this means having relatively little prostate cancer–related pain and not needing narcotics to treat cancer-related pain

narcotics: substances that relieve pain

nausea: feeling sick to the stomach, often accompanied by an urge to vomit

**prostate-specific antigen (PSA):** a protein made by the prostate gland and by prostate cancer. A test for PSA is often used to screen for prostate cancer and to monitor some treatments for the disease

**recombinant antigen:** a protein that is designed to produce an immune response. With PROVENGE, this is an immune response to prostate cancer

sterility: being free from living germs and other microscopic organisms

 ${\sf T}$  cells: a type of immune cell that helps the immune system fight disease such as viral infections and cancer

