

**PROVENGE**<sup>®</sup>  
(sipuleucel-T)

# Activate your immune system

TO FIGHT ADVANCED  
PROSTATE CANCER



# Speaker disclosure

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# What you need to know

- 1 Role of the immune system in cancer
- 2 PROVENGE® (sipuleucel-T): The only FDA-approved immunotherapy designed to seek out and attack your prostate cancer
- 3 PROVENGE treatment process
- 4 Empower yourself to take action





# 2.

## Role of the immune system in cancer

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# What is the immune system?

*The immune system recognizes and eliminates abnormal cells*



The **immune system** is a network of cells that work together to protect your body from harmful intruders such as infections or abnormal cells, like cancer cells<sup>1</sup>



**Immunotherapy** in prostate cancer is a type of treatment that **works with your immune system**<sup>2</sup>

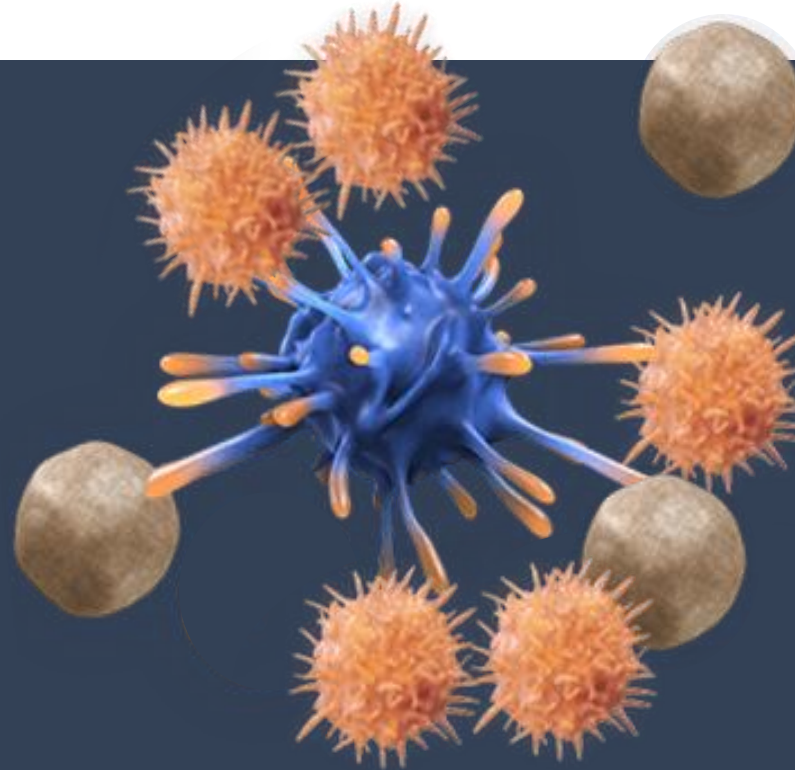
1. Marshall, J.S., et al. *Allergy Asthma Clin Immunol.* 14 (Suppl 2), 49 (2018).

2. Bou-Dargham, M.J., et al. *BMC Cancer* 20, 572 (2020).

# Why is an activated immune system important?

*The immune system may help prevent cancer cells from growing into tumors<sup>1</sup>*

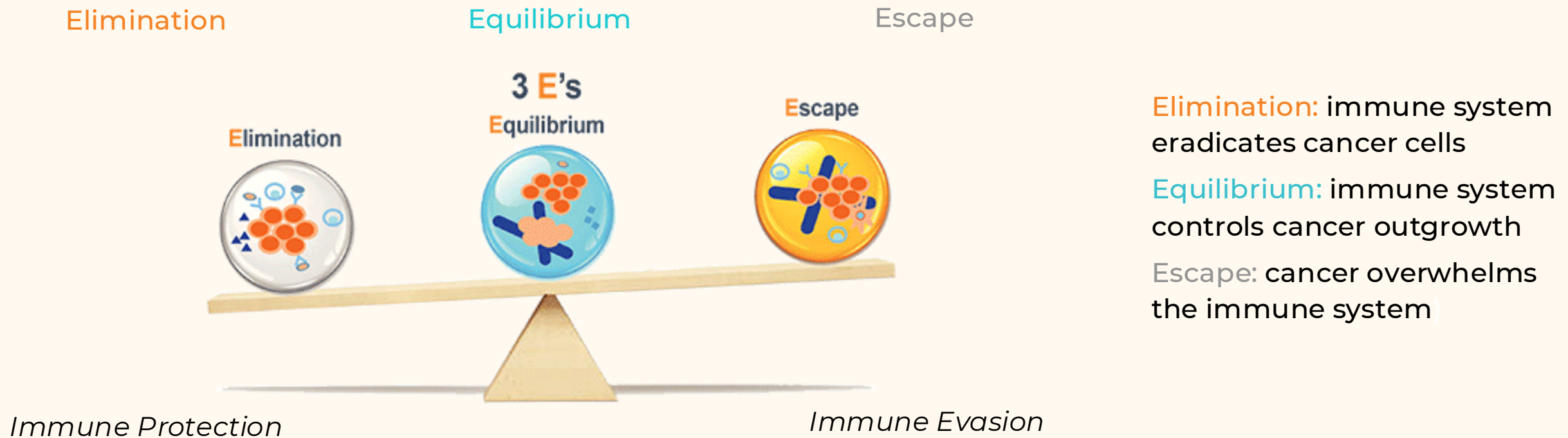
An activated immune system may help prevent the development of cancer and eliminate cells before they can grow and spread<sup>1,2</sup>



1. Loose D, et al. *Cancer Biother Radiopharm.* 2009;24(3):369-376. 2. Kumar AR, et al. *Mol Biol Rep.* 2021;48(12):8075-8095.

# Cancer evades and overwhelms the immune system

The immune system and cancer interact in a dynamic process, known as the **3 E's**

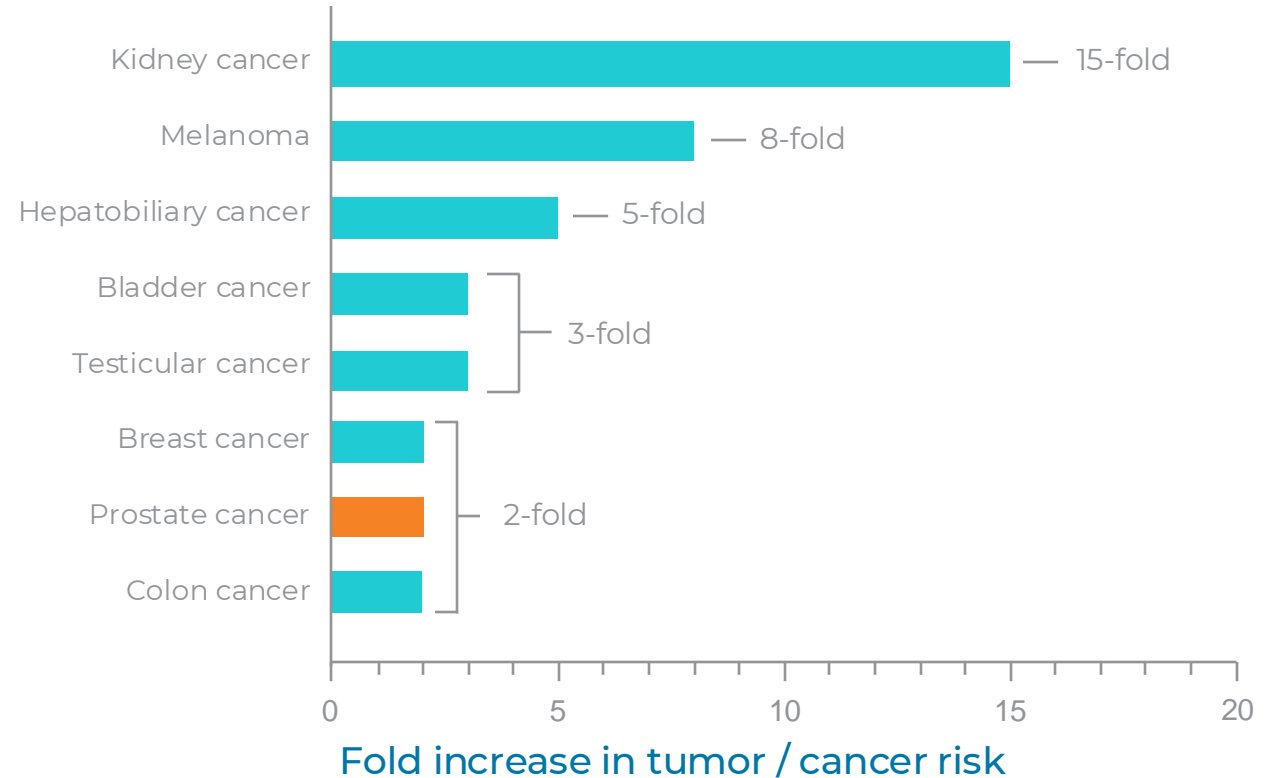


Immunotherapy can boost or restore the ability of the immune system to fight against invaders like infections and abnormalities, like some cancer cells<sup>1</sup>

# A compromised immune system can lead to cancer

- Malignant tumors can develop in individuals with a compromised immune system, such as transplant patients<sup>1-3</sup>
- Individuals with a compromised immune system have a higher risk of developing complications and have an increased risk of cancer<sup>4</sup>

Tumor / Cancer Risk In Transplant Patients Compared With General Population<sup>1</sup>



1. Kasiske BL, Wang C, et al. *Am J Transplant*. 2004;4(6):905-913. 2. Le Mire L, Wojnarowska F, et al. *Br J Dermatol*. 2006;154(3):472-477.

3. Abbas AK, Lichtman AH. In: *Basic Immunology*. 3rd ed. 2011. 4. Mortaz E, et al. *Front Immunol*. 2016;7:365.



# Increased immune cells in tumors improve survival

When your immune system is activated, it may help fight cancer cells more effectively, possibly helping you live longer<sup>2-5</sup>

## DIFFERENT TYPES OF IMMUNE CELLS WORK TOGETHER TO RECOGNIZE AND ELIMINATE CANCER CELLS<sup>1</sup>



Killer T-Cells



Antigen-Presenting Cells (APCs)



Antigen



Antibodies

- Research has shown that using a combination of treatments, including immunotherapy, may lead to a better response against large metastatic tumors<sup>2</sup>
- In some studies, patients with more T-cells in their tumor, lived longer<sup>2-4</sup>

1. Abbas AK, Lichtman AH. In: *Basic Immunology*. 3rd ed. 2011. 2. Zhang L, et al. *N Engl J Med*. 2003;348(3):203-213. 3. Galon J, et al. *Science*. 2006;313(5795):1960-1964. 4. Gonzalez H, et al. *Genes Dev*. 2018;32(19-20):1267-1284. 5. Nanoparticle Trains Immune Cells to Attack Cancer. <https://www.cancer.gov/news-events/cancer-currents-blog/2020/nanoparticle-trained-immunity-cancer-immunotherapy>.

# In summary

The immune system recognizes and eliminates abnormal cells



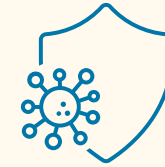
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Immune system and cancer cells interact in a dynamic process, known as the 3 E's: elimination, escape, equilibrium<sup>1,2</sup>



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When your immune system is activated, it may fight cancer cells more effectively, possibly helping you live longer<sup>3</sup>



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Immunotherapy may help the immune system to re-engage in fighting cancer<sup>3</sup>

1. Dunn GP, Schreiber RD, et al. *Nat Rev Immunol*. 2006;6(11):836-848. 2. Murphy K. In: *Janeway's Immunobiology*. 8th ed. 2012. 3. Gonzalez H, et al. *Genes Dev*. 2018;32(19-20):1267-1284.

2.

PROVENGE: The only FDA-approved immunotherapy designed to seek out and attack your prostate cancer

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**PROVENGE**<sup>®</sup>  
(sipuleucel-T)

# PROVENGE<sup>®</sup> (sipuleucel-T) overview



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PROVENGE is a prescription medicine used to treat men with advanced prostate cancer



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PROVENGE is a personalized immunotherapy made from your own immune cells that empowers your body's immune system to recognize and attack your prostate cancer cells

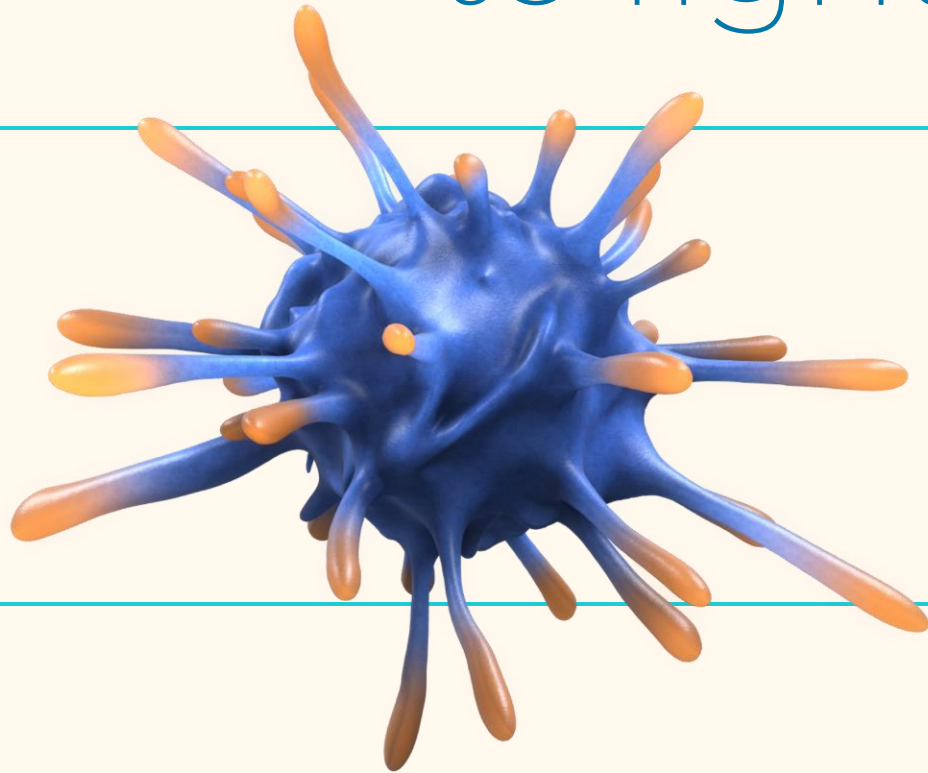


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Multiple studies indicate that using PROVENGE may help you live longer



# more strength to fight back

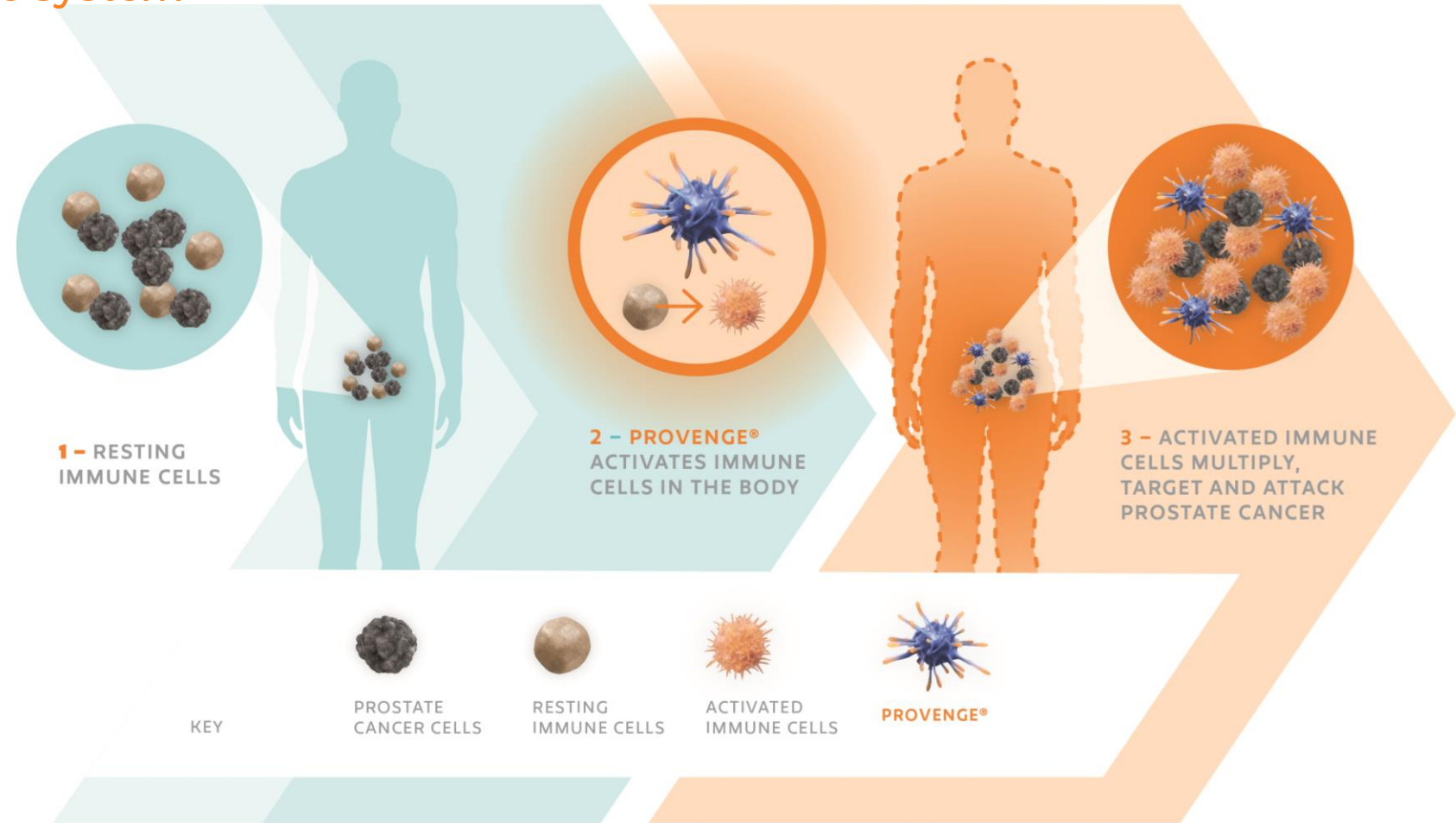


Since FDA approval in 2010,  
nearly **40,000** men have  
received PROVENGE®  
(sipuleucel-T)

# PROVENGE® (sipuleucel-T) immunotherapy

## More power for your immune system

- PROVENGE is a personalized immunotherapy made from your own immune cells that empowers your body's immune system to recognize and attack your prostate cancer cells
- PROVENGE has been clinically proven to extend life in certain men with advanced prostate cancer



# Patients who received PROVENGE® (sipuleucel-T) lived longer than patients who did not receive PROVENGE

The FDA approval study of PROVENGE, IMPACT, consisted of 512 men with mCRPC and compared men who received PROVENGE to men who did not.

Men who took PROVENGE® lived a median of 4.1 months longer<sup>1</sup>

MEN TAKING PROVENGE\*

25.8 months

MEN NOT TAKING PROVENGE\*

21.7 months

*\*Individual results may vary*

*At the time of this trial, the only treatment options for mCRPC were ADT and chemotherapy. The average life expectancy for men with mCRPC was 12-18 months<sup>1,2</sup>*

ADT, androgen deprivation therapy; FDA, Food and Drug Administration

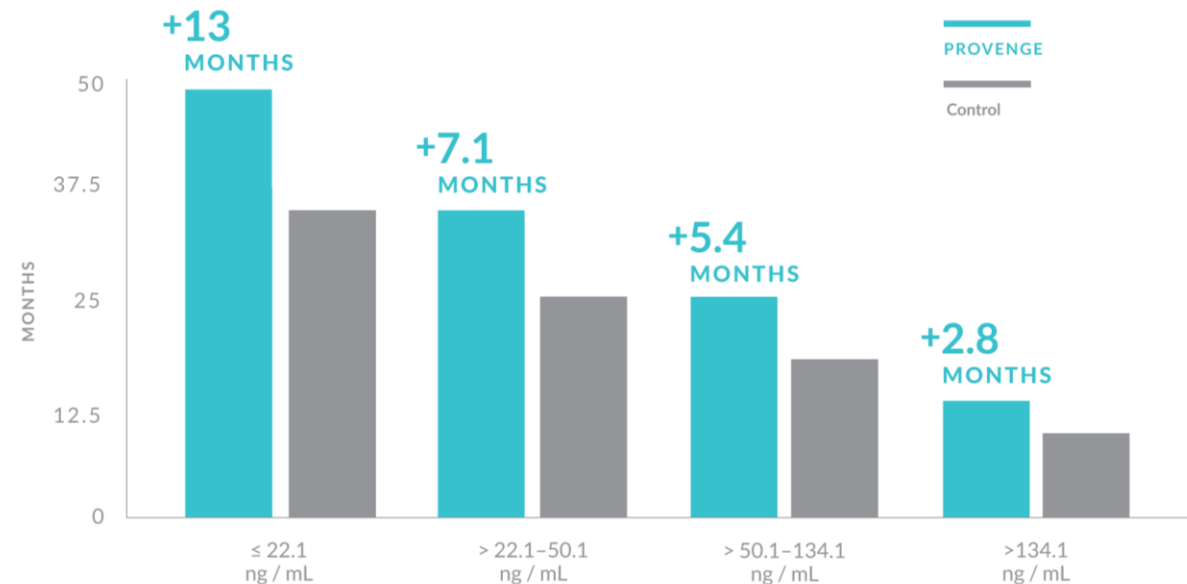
1. Kantoff PW, et al. *N Engl J Med.* 2010;363(5):411-422. 2. Chin S, et al. *Curr Oncol.* 2010;17(2):24-29.

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**IMPORTANT SAFETY INFORMATION (Continued):** Thromboembolic Events: Thromboembolic events, including deep venous thrombosis and pulmonary embolism, can occur following infusion of PROVENGE. The clinical significance and causal relationship are uncertain. Most patients had multiple risk factors for these events. PROVENGE should be used with caution in patients with risk factors for thromboembolic events

# Studies suggest treating earlier with PROVENGE® (sipuleucel-T) when their baseline PSA is lower may help patients live longer

- Studies suggest men who received PROVENGE with a baseline PSA level of  $\leq 22.1$  ng/mL lived a median of **13 months longer** compared to men who did not<sup>1</sup>
- Many nationally respected guidelines recommend early use of PROVENGE to treat mCRPC<sup>2,3</sup>



This post hoc analysis was not powered for statistical significance, and the population within the subgroups was not randomized. Therefore, the findings are limited by their exploratory nature.

**IMPORTANT SAFETY INFORMATION (Continued):** Vascular Disorders: Cerebrovascular events (hemorrhagic/ischemic strokes and transient ischemic attacks) and cardiovascular disorders (myocardial infarctions) have been reported following infusion of PROVENGE. The clinical significance and causal relationship are uncertain. Most patients had multiple risk factors for these events. Handling Precautions: PROVENGE is not tested for transmissible infectious diseases

Please see Important Safety Information and full Prescribing Information available at this presentation

mCRPC, metastatic-resistant prostate cancer; PSA, prostate-specific antigen;

1. Schellhammer PF, et al. *Urology*. 2013;81(6):1297-1302. 2. Lowrance W, et al. *J Urol*. 2023;209(6).

3. Crawford ED, et al. *Urology*. 2017;104:150-159



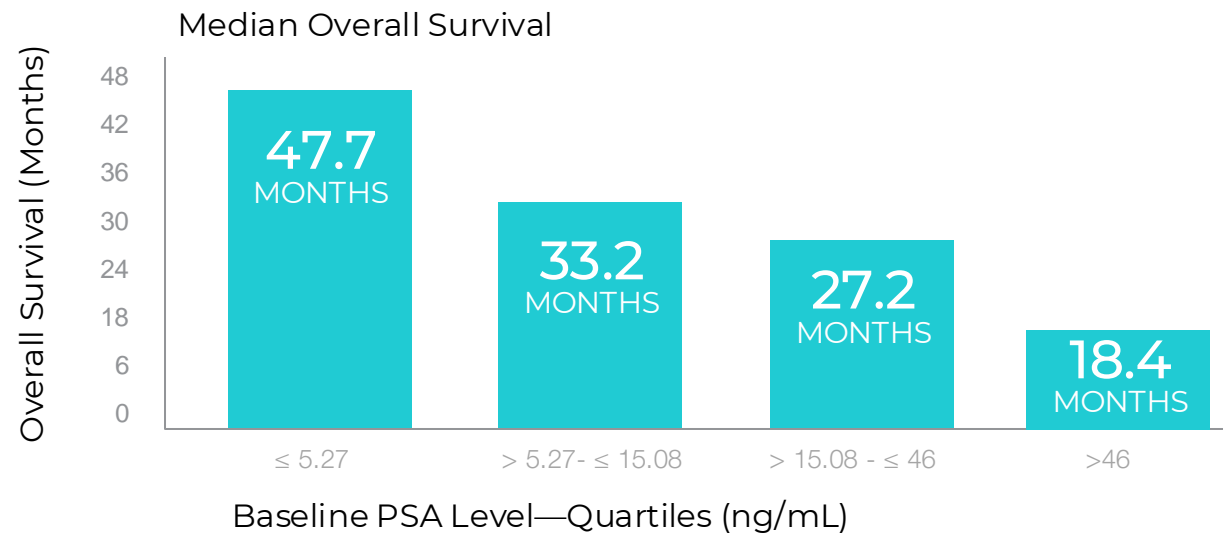
# Real-world data in men who were treated with PROVENGE® (sipuleucel-T) when their PSA was lower<sup>1</sup>

- The PROCEED registry observed 1,976 men with mCRPC who received PROVENGE
- Men taking PROVENGE with a median baseline PSA level of  $\leq 5.27$  ng/mL lived **a median of about 4 years**

*The PROCEED registry evaluated the expected safety and survival profile of PROVENGE received by patients in the real-world setting in which there was no control group. Patients may have received additional anti-cancer interventions.*

mCRPC, metastatic castration-resistant prostate cancer; PSA, prostate-specific antigen; PROCEED, PROVENGE Registry for the Observation, Collection, and Evaluation of Experience Data  
1. Higano CS, et al. *Cancer*. 2019;125(23):4172-4180.

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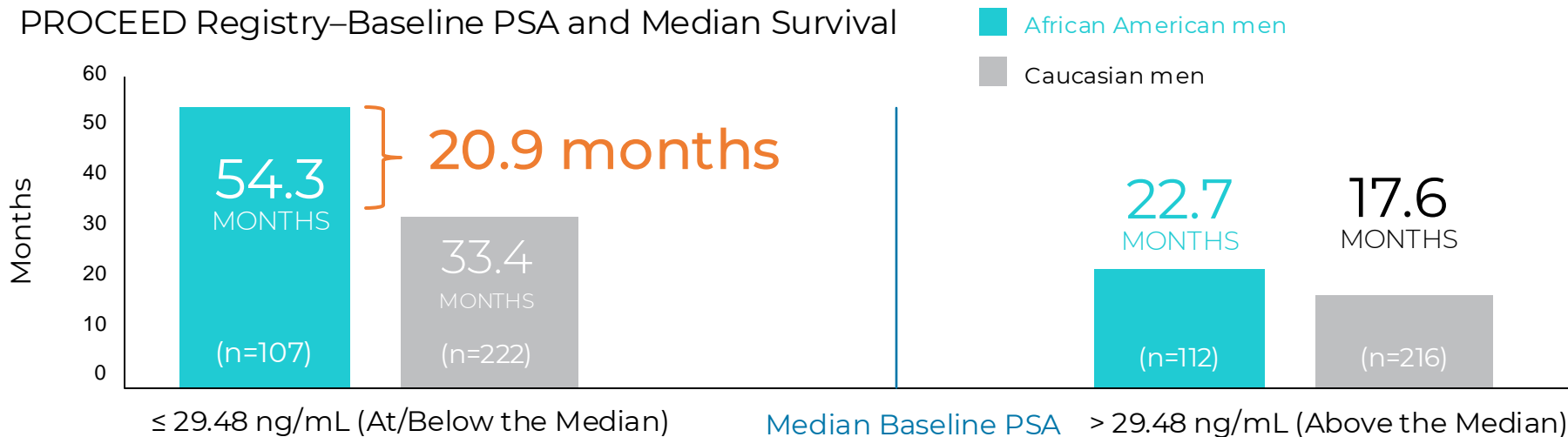


*Analysis was exploratory and individual results may vary.*

**IMPORTANT SAFETY INFORMATION (Continued):** Concomitant Chemotherapy or Immunosuppressive Therapy: Chemotherapy or immunosuppressive agents (such as systemic corticosteroids) given concurrently with the leukapheresis procedure or PROVENGE has not been studied. Concurrent use of immune-suppressive agents may alter the efficacy and/or safety of PROVENGE. Adverse Reactions: The most common adverse reactions reported in clinical trials ( $\geq 15\%$  of patients receiving PROVENGE) were chills, fatigue, fever, back pain, nausea, joint ache, and headache. Please see Important Safety Information and full Prescribing Information available at this presentation

# Real-world data in African American patients<sup>1</sup>

African American men have a higher risk of prostate cancer. A follow-up analysis of the PROCEED registry looked at survival data in African American men, compared to Caucasian men



African American men taking PROVENGE when their baseline PSA was  $\leq 29.48$  ng/mL had a median survival of 54.3 months — 20.9 months longer than Caucasian men

The PROCEED registry evaluated the expected safety and survival profile of PROVENGE® received by patients in the real-world setting in which there was no control group. The study was conducted to quantify the risk of cerebrovascular events and, secondarily, survival. Patients may have received subsequent anti-cancer interventions per the local investigator's standard of care. This subgroup analysis of the PROCEED registry was exploratory, and results need careful interpretation.

PSA, prostate-specific antigen ; PROCEED, PROVENGE Registry for the Observation, Collection, and Evaluation of Experience Data

1. Sartor O, et al. *Prostate Cancer Prostatic Dis.* 2020;23(3):517-526.

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Analysis was exploratory and individual results may vary.

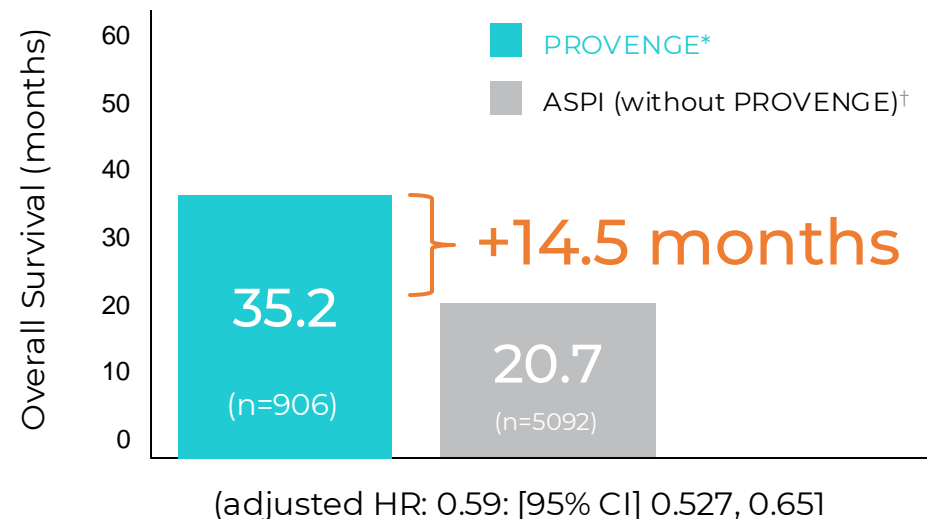
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# Real-world evidence for PROVENGE® (sipuleucel-T)

The use of PROVENGE at any time is associated with improved overall survival and ability to receive more lines of additional treatment<sup>1</sup>

## A retrospective cohort analysis using US Medicare claims data to evaluate OS in 6,044 men with a prostate cancer diagnosis from 2013-2017<sup>1</sup>

- Observed median overall survival was 35.2 months with any-line PROVENGE versus 20.7 months with any-line ASPIs—a 14.5-month difference in overall survival.
- Men receiving PROVENGE (n=179) were 2.5 times more likely to receive 4 additional lines of therapy vs. men receiving ASPIs but not PROVENGE (n=393).



A PROVENGE group = patients who received PROVENGE at any time. They also could have received other agents.  
†ASPI (without PROVENGE) = patients who received ASPIs in any line, but not PROVENGE. They also could have received other agents.  
ASPI, androgen-receptor signaling pathway inhibitor; OS, overall survival; CI, confidence interval; HR, hazard ratio.

1. McKay RR, et al. *Adv Ther.* 2020;37(12):4910-4929. .

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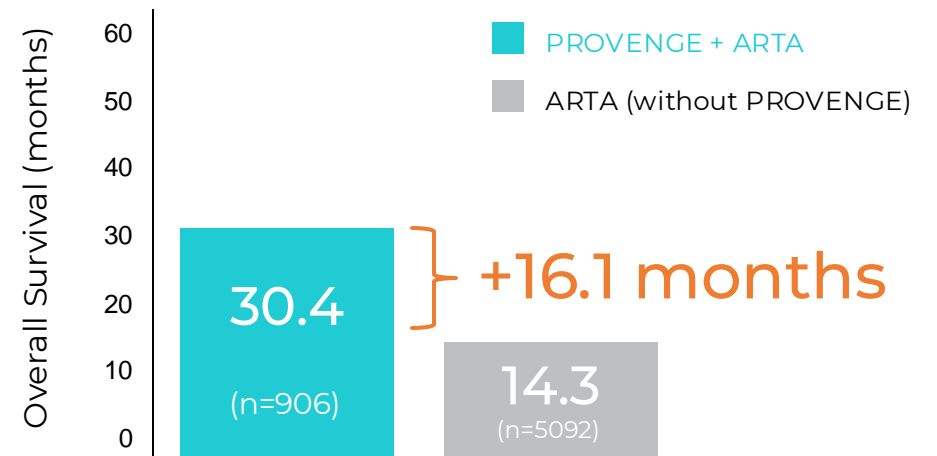
Claim analyses like these are limited in their ability to reliably predict treatment effects, and individual results may vary. This claims dataset does not include certain safety or clinical assessments; the analysis was exploratory, and the results need careful interpretation.

# Real-world evidence for PROVENGE® (sipuleucel-T)

PROVENGE-treated patients lived longer than patients not receiving PROVENGE at any line of use<sup>1</sup>

## A retrospective cohort analysis using US Medicare claims data to evaluate OS in 5,415 men with mCRPC<sup>1</sup>

- Median overall survival was 30.4 months in men with mCRPC who received PROVENGE and an ARTA and 14.3 months in men who got only ARTA monotherapy – a 16.1-month difference
- Median overall survival in men receiving PROVENGE + ARTA was 16 months longer than those receiving only ARTA<sup>a</sup>.



Additional studies, STAMP and STRIDE, have shown that PROVENGE can be administered before, or with oral ARTAs<sup>2,3</sup>

a: ARTAs include abiraterone acetate plus prednisone and enzalutamide  
ARTA, androgen receptor-targeted agents; mCRPC, metastatic castration-resistant prostate cancer; OS, overall survival.

1. Hafron JM, et al. *Adv Ther*. 2022;39(6):2515-2532. 2. <https://clinicaltrials.gov/ct2/show/NCT01487863>.  
3. <https://clinicaltrials.gov/ct2/show/NCT01981122>.

Claim analyses like these are limited in their ability to reliably predict treatment effects, and individual results may vary. This claims dataset does not include certain safety or clinical assessments; the analysis was exploratory, and the results need careful interpretation.



# PROVENGE® (sipuleucel-T): A personalized immunotherapy

## PROVENGE®: the first FDA-approved immunotherapy to treat mCRPC

### 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 about 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<sup>®</sup> (sipuleucel-T): A personalized immunotherapy

PROVENGE<sup>®</sup>: the first FDA-approved immunotherapy to treat mCRPC

PROVENGE<sup>®</sup> 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
- 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](http://www.fda.gov/medwatch) or call [1-800-FDA-1088](tel:1-800-FDA-1088).

Please refer to the full Prescribing Information provided at the program.

# The PROVENGE difference

**PROVENGE® (sipuleucel-T) is well-tolerated. The use of other medications does not limit the use of PROVENGE**

## How may I feel while taking PROVENGE?

The most common side effects of PROVENGE® were generally mild to moderate and were well tolerated

1.5% of patients discontinued treatment in clinical trials because of adverse events

Treatment can be completed within 6 appointments within about a month

**IMPORTANT SAFETY INFORMATION (Continued):** Acute Infusion Reactions: Acute infusion reactions (reported within 1 day of infusion) may occur and include nausea, vomiting, fatigue, fever, rigor or chills, respiratory events (dyspnea, hypoxia, and bronchospasm), syncope, hypotension, hypertension, and tachycardia.

PROVENGE [prescribing information]. Seal Beach, CA: Dendreon Pharmaceuticals LLC; 2017.

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# 3. PROVENGE<sup>®</sup> (sipuleucel-T) treatment process



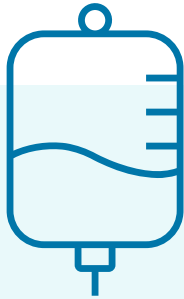
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**PROVENGE<sup>®</sup>**  
(sipuleucel-T)

Please see Important Safety Information and full Prescribing Information available at this presentation.

# Infusion

PROVENGE® (sipuleucel-T) the only FDA-approved immunotherapy designed to seek out and attack your prostate cancer and has been proven to help men live longer



The intravenous (IV) infusion of PROVENGE® will take place at your healthcare provider's office or infusion center.



You may be premedicated with oral acetaminophen and an oral antihistamine based on the preference of the physician.



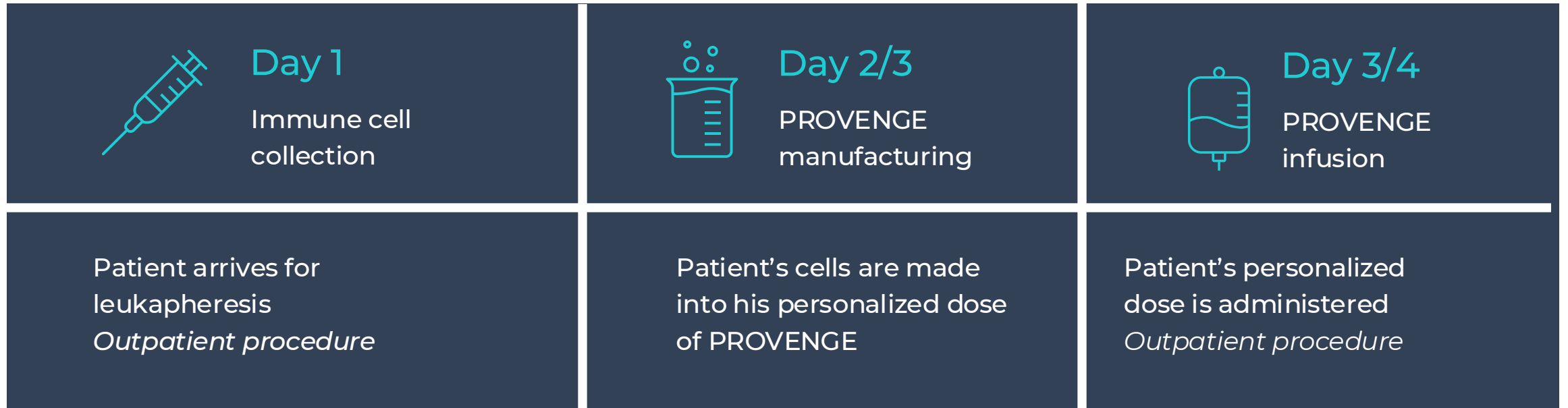
The process itself takes about 1 hour, followed by 30 minutes of post-infusion monitoring.

**IMPORTANT SAFETY INFORMATION (Continued):** Thromboembolic Events: Thromboembolic events, including deep venous thrombosis and pulmonary embolism, can occur following infusion of PROVENGE. The clinical significance and causal relationship are uncertain. Most patients had multiple risk factors for these events. PROVENGE should be used with caution in patients with risk factors for thromboembolic events



# Treatment

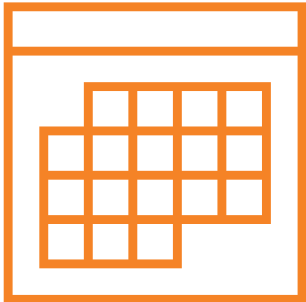
Each dose of PROVENGE® (sipuleucel-T) is designed specifically for each patient



*This process is repeated 2 more times for a total of 3 treatments*

# The PROVENGE journey

A dedicated Dendreon nurse will be available to help guide you through the entire treatment process



- A course of PROVENGE<sup>®</sup> (sipuleucel-T) treatment consists of **6 appointments** (3 cell collections and 3 infusions) that can be completed in as quickly as a month
- Dosing intervals between infusions can be **flexible to fit your life and schedule**. In controlled clinical trials, the dosing interval was between 1 and 15 weeks with no maximum interval being established

# Are you eligible for PROVENGE® (sipuleucel-T)?

## Do you meet the clinical criteria?

- You are considered **castration resistant** (CRPC) which means your cancer has progressed while on androgen deprivation therapy (ADT)
- Your testosterone level is **less than or equal to 50 ng/dL**
- Your cancer has spread and is confirmed as **metastatic disease**
- You are **not taking narcotics** for cancer-related pain

ADT, androgen deprivation therapy

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# In summary



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PROVENGE® (sipuleucel-T) is the only FDA-approved immunotherapy that is designed to target prostate cancer and extends overall survival



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PROVENGE is a personalized medicine made from your own immune cells that targets PAP, which is an antigen found on 95% of prostate cancer cells



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PROVENGE treatment consists of **6 appointments** that can be done in **approximately 1 month**

**IMPORTANT SAFETY INFORMATION (Continued):** Concomitant Chemotherapy or Immunosuppressive Therapy: Chemotherapy or immunosuppressive agents (such as systemic corticosteroids) given concurrently with the leukapheresis procedure or PROVENGE has not been studied. Concurrent use of immune-suppressive agents may alter the efficacy and/or safety of PROVENGE. Adverse Reactions: The most common adverse reactions reported in clinical trials ( $\geq 15\%$  of patients receiving PROVENGE) were chills, fatigue, fever, back pain, nausea, joint ache, and headache. Please see Important Safety Information and full Prescribing Information available at this presentation



4.

Empower  
yourself to  
take action

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**PROVENGE**<sup>®</sup>  
(sipuleucel-T)



# importance of monitoring your disease

~20-30% of men who received initial localized therapy for prostate cancer experience a recurrence but exhibit no symptoms<sup>1</sup>

1. Punnen S, et al. *Eur Urol*. 2013;64(6):905-915.

# Following up with your physician

- Have your physician schedule regular blood tests (monitoring PSA level) or radiographic scans at regular intervals, as these are important to monitor for signs that the cancer has returned
- Tell your doctor if you are experiencing any unusual symptoms as they indicate a change in your health

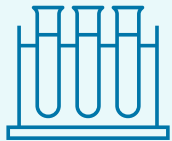
PSA, prostate-specific antigen

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# 3 types of testing to monitor disease

It is important to get regular screening recommended by your doctor to receive the right treatment at the right time



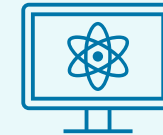
PSA testing<sup>1</sup>

- Disease progression may occur without a rise in PSA.
- Approximately 25% of patients had cancer progression when their PSA levels stayed the same.<sup>3</sup>



Testosterone testing<sup>1,2</sup>

Testosterone testing should be done to confirm your prostate cancer is responsive to hormone therapy



Imaging<sup>1</sup>

Using imaging can help with detecting cancer metastasis early<sup>1</sup>

PSA, prostate-specific antigen

1. Lowrance W, et al. *Urol.* 2023;209(6):10. 2. Shayegan B, et al. *Can Urol Assoc J.* 2017;11(6):204-209. 3. Bryce AH, et al. *Eur Urol Oncol.* 2020;3(6):717-724.

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# Get the most out of your appointments

- Bring a care partner with you
- Write down questions before your appointment
- Be open and honest about your needs and concerns
- Follow up with prescriptions, lab work, or tests
- Sign up for online portal to access your tests and records
- Keep a journal of questions, current medications, names of other HCPs, and notes about your health



# Talk to your cancer care doctor about PROVENGE® (sipuleucel-T)

- PROVENGE helps men with mCRPC live longer
- The most common side effects were generally mild to moderate and were well-tolerated
- PROVENGE works differently from other cancer treatments, such as chemotherapy or hormone therapy, since it is more personalized to you
- PROVENGE is covered by Medicare and by most private insurance plans

Visit [PROVENGE.COM](https://www.provenge.com)  
to find a urologist or  
oncologist who can  
administer PROVENGE

Abbreviations: mCRPC, metastatic castration-resistant prostate cancer

PROVENGE [prescribing information]. Seal Beach, CA: Dendreon Pharmaceuticals LLC; 2017



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- Have signs of a stroke, such as numbness or weakness on one side of the body, decreased vision in one eye, or difficulty speaking
- 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](http://www.fda.gov/medwatch) or call [1-800-FDA-1088](tel:1-800-FDA-1088).

Please refer to the full Prescribing Information provided at the program.



Message from a  
patient ambassador

# Patient ambassador speaker disclosure

While I am being compensated by Dendreon for being here, I hope my story will encourage you to advocate for yourself no matter where you are in your journey with prostate cancer. Please keep in mind, what I share with you today is my experience. Yours may be different.



# Euvon

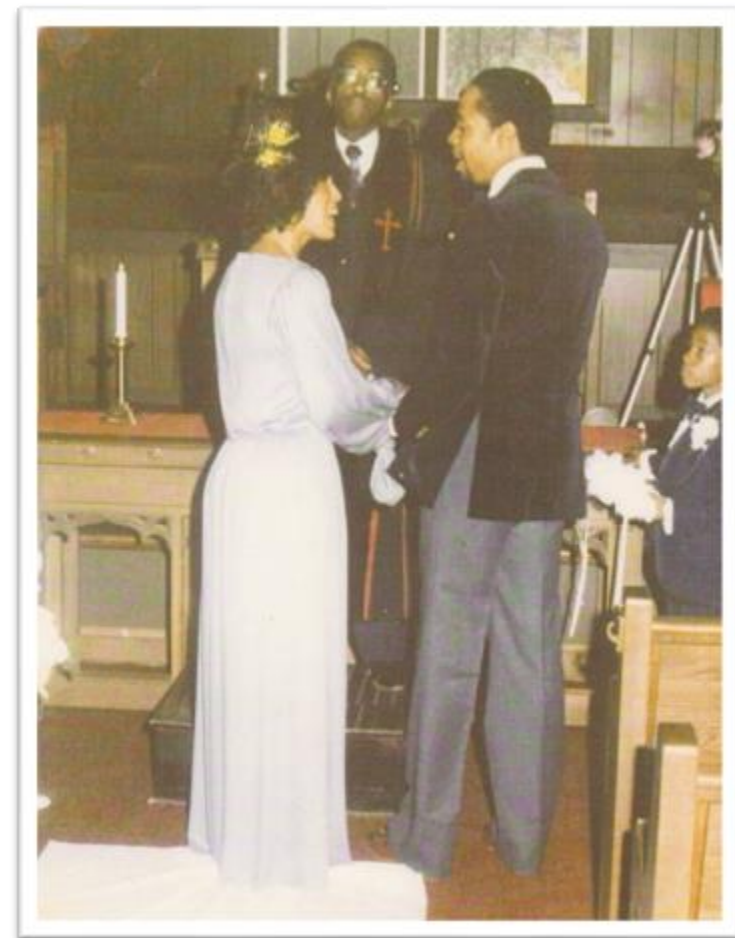
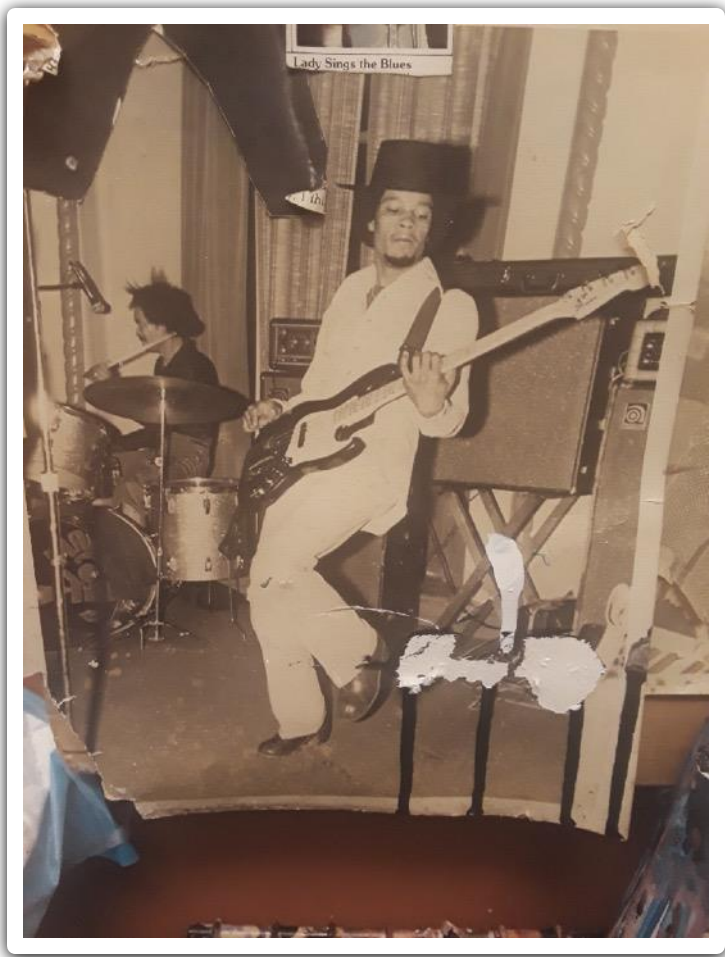
Euvon is a promotional speaker compensated by Dendreon.

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# Thank You

I am a promotional speaker for Dendreon. For medical advice, please consult your own healthcare provider.

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# Questions?

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