Real-World Evidence

SUPPORTING THE USE OF PROVENGE® (sipuleucel-T)

in African American Men With Advanced Prostate Cancer

Prostate cancer is the most frequently occurring non-cutaneous cancer among men in the United States and is second only to lung cancer among the leading causes of cancer-related deaths.[1]

Prostate cancer disproportionately impacts African American men:

One out of 7 **will be diagnosed** with prostate cancer in their lifetime.[1]

2.5 times **more likely to die** from prostate cancer than Caucasian men.[1]

Are **diagnosed at a younger age**, tend to have **more advanced disease** when it is found, and tend to have a **more severe type of prostate cancer** than other men.[2]

In **IMPACT**, the pivotal, double-blind, placebo-controlled trial that supported FDA approval of PROVENGE (sipuleucel-T), median overall survival (OS) was greater in men who received PROVENGE. Men with metastatic castrate-resistant prostate cancer (mCRPC) were randomly assigned to receive PROVENGE or a placebo. In men treated with PROVENGE, median OS was **25.8 months compared to 21.7 months in the control group.**[3]

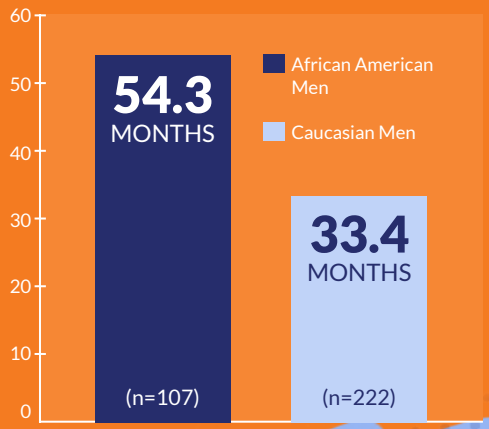
The PROCEED Registry (NCT01306890):[4,5]

- Real-world, observational registry of men with prostate cancer conducted at urology and medical oncology clinics across the country.
- Enrolled 1,976 patients with metastatic castrate-resistant prostate cancer (mCRPC).
  - Median age was 72 years; median baseline PSA was 15.0 ng/mL
  - 12 percent of patients were African American
- Patients received PROVENGE between 2011 and 2017 in everyday treatment settings
- Median follow time was 46.6 months

In the PROCEED Registry:

- Median OS for all men was **more than 2.5 years** (30.7 months)[4,5]
- For men who were treated when their PSA was low, median survival was **nearly 4 years**[4,5]
- In a PSA matched subset, median OS was nearly 3 years for all African American men - 9.5 months longer than Caucasian men (data not shown)[4,5]
- In a PSA matched subset, African American men with PSA below the median treated with PROVENGE **lived over 4.5 years**, compared with 2.8 years for Caucasian men — a difference of 20.9 months[4,5]

Overall Survival in PSA-Matched Men with Baseline PSA At/Below the Median (≤29.48 ng/mL)[a,b]



a. This subgroup analysis of the PROCEED registry was exploratory and results need careful interpretation.
b. Baseline PSA levels were significantly different between African American men and Caucasian men. Thus, Caucasians were matched (2:1) to African Americans with baseline PSA levels within ± 10% of the Caucasian baseline PSA value, to minimize the effect of this clinical imbalance on survival.

INDICATION

PROVENGE® (sipuleucel-T) is an autologous cellular immunotherapy indicated for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

Please see Important Safety Information continued below and the link to the full Prescribing Information.

PROVENGE (sipuleucel-T) is a personalized immunotherapy that activates the immune system to help fight advanced prostate cancer and has been proven to help certain men live longer.[6]

- **40,000+** men have been prescribed to date[6]
- PROVENGE has been shown to increase overall survival and generate patient-specific immune responses that correlate with increased overall survival.[6]
- The most common side effects (95%) of PROVENGE are generally mild to moderate, including fevers and chills, which were typically resolved within 2 days (71.9% and 89%, respectively).[6]

To learn more about the PROCEED Registry and PROVENGE®, visit www.StartStrong.us.

IMPORTANT SAFETY INFORMATION

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.

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.

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.

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 (≥ 15% of patients receiving PROVENGE) were chills, fatigue, fever, back pain, nausea, joint ache, and headache.

Click here for full Prescribing Information..

1. American Cancer Society. Cancer Facts & Figures for African Americans 2019-2021. Accessed June 6, 2021. https://www.cancer.org/research/cancer-facts-statistics/cancer-facts-figures-for-african-americans.html 2. Centers for Disease Control and Prevention. Prostate Cancer. Accessed June 6, 2021. https://www.cdc.gov/cancer/prostate/basic_info/risk_factors.htm 3. Kantoff PW, Higano CS, Shore ND, et al; IMPACT Study Investigators. Sipuleucel-T immunotherapy for castration-resistant prostate cancer. N Engl J Med. 2010;363(5):411-422. doi:10.1056/NEJMoa1001294 4. Sartor O, et al. Overall Survival Analysis of African American and Caucasian Patients Receiving Sipuleucel-T: Preliminary Data from the PROCEED Registry. Presented at the 2017 American Urological Association (AUA) Annual Meeting; May 13, 2017; Boston, Mass. 5. Higano CS, et al. Real-world outcomes of sipuleucel-T treatment in PROCEED, a prospective registry of men with metastatic castration-resistant prostate cancer. Cancer. 2019;125(23):4172-4180. doi:10.1002/cncr.32445 6. PROVENGE [Patient Brochure]. Seal Beach, CA: Dendreon Pharmaceuticals LLC; 2019.

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