Booster infusion of sipuleucel-T in metastatic castrate resistant prostate cancer (mCRPC)

Prov·ONE

Dendreon Study ID: P23-1

ClinicalTrials.gov Identifier: NCT06134232

ProvONE: A Phase 2, Open-Label, Multicenter Study of Subjects With Metastatic Castrate-Resistant Prostate Cancer Treated With PROVENGE® and Boosted With A Single Infusion of Sipuleucel-T to Measure Immune Response

Primary Objective

- Assess the humoral response of PAP and PA2024 after booster infusion in subjects with mCRPC who have received a single booster dose of sipuleucel-T vs those subjects who have not

Secondary Objective

- Evaluate overall survival (OS) after booster infusion of sipuleucel-T
- Evaluate the safety and tolerability of a single booster dose of sipuleucel-T

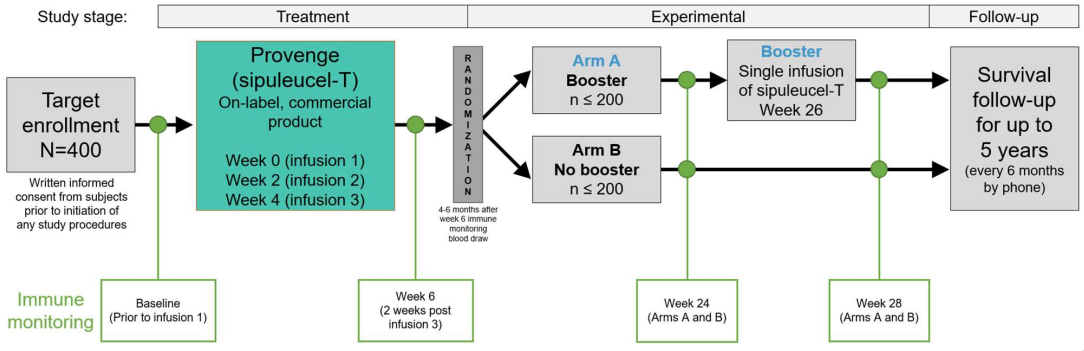
Key Inclusion Criteria

- ≥18 years old who are clinically indicated for treatment with Provenge (asymptomatic or minimally symptomatic metastatic castrate-resistant [hormone refractory] prostate cancer)
- Qualify for on-label Provenge
- Have received all 3 infusions of Provenge prior to randomization
- Written informed consent provided prior to initiation of study procedures
- Estimated life expectancy ≥12 months

Key Exclusion Criteria

- Men who are not clinically indicated for treatment with Provenge (asymptomatic or minimally symptomatic metastatic castrate-resistant [hormone refractory] prostate cancer)
- Need for systemic chronic immunosuppressive therapy (eg, antitumor necrosis factor alpha monoclonal antibodies, or glucocorticoids)
- Uncontrolled, concurrent illness including, but not limited to the following: ongoing or active infection (bacterial, viral, or fungal), or psychiatric illness that would limit compliance with study requirements, as well as any condition that would preclude a subject from completing Provenge or sipuleucel-T treatment
- On experimental or investigational therapy

Study Design



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Summary: ProvONE is an open-label, randomized, controlled clinical trial that will evaluate immune responses, survival, safety, and tolerability of an additional booster sipuleucel-T infusion after receiving on-label Provenge. There are two stages to the study: a treatment stage and experimental stage. All subjects in the study will receive on-label Provenge as part of the Treatment stage. Subjects randomized to the Booster arm for the Experimental stage will receive one additional booster sipuleucel-T infusion.

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.

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.

FOR MORE INFORMATION ABOUT PROVONE

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CONTACT

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Booster dose of sipuleucel-T during the experimental stage has not been approved for use outside of the clinical trial setting. The safety and efficacy of a booster dose of sipuleucel– T have not been established. This information is provided for your information only and should not be regarded as a recommendation. Dendreon does not recommend or intend any of its products to be used in a manner that may be inconsistent with approved product labeling.

MEDICAL AFFAIRS

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