AN 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

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INVESTIGATIONAL PHASE:	2
PROTOCOL NUMBER:	P23-1
INVESTIGATIONAL PRODUCT:	Sipuleucel-T
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Study Population and Sample Size

Potential subjects are men aged ≥18 years who are clinically indicated for treatment with Provenge.

Following the completion of Provenge regimen, up to 400 subjects will be randomized 1:1 to either the Booster arm or the Control arm.

Inclusion Criteria

For a subject to be eligible for participation in this study, *all* of the following criteria must be satisfied.

1. Potential subjects are men aged ≥18 years who are clinically indicated for treatment with Provenge (asymptomatic or minimally symptomatic metastatic castrate-resistant [hormone refractory] prostate cancer)
2. Have qualified for on-label Provenge infusion
3. Have received all 3 infusions of Provenge prior to randomization
4. Written informed consent provided prior to the initiation of study procedures
5. Estimated life expectancy ≥12 months

Exclusion Criteria

A subject will not be eligible for participation in this study if *any* of the following criteria apply.

1. Men who are <u>not</u> clinically indicated for treatment with Provenge (asymptomatic or minimally symptomatic metastatic castrate-resistant [hormone refractory] prostate cancer)
2. Need for systemic chronic immunosuppressive therapy, including antitumor necrosis factor alpha monoclonal antibodies, glucocorticoids, systemic steroids, blood products, GM-CSF or granulocyte colony-stimulating factor (G-CSF), any vaccinations, or experimental and investigational therapies (See Section 6.3.1)
3. 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
4. On experimental or investigational therapy