Title: **Open- Label Trial of Sipuleucel-T Administered to Active Surveillance Patients for Newly Diagnosed Prostate Cancer (ProVent)**

Sponsor:
Dendreon

Brief Summary	The ProVent study is a randomized, open-label study designed to assess the efficacy of sipuleucel-T in reducing the progression of lower risk non-metastatic prostate cancer compared to subjects followed on active surveillance as standard of care.
Study Type	Interventional
Study Arms	• Experimental: Treatment Group: Sipuleucel-T Sipuleucel-T is an autologous cellular immunotherapy available as a suspension for intravenous infusion. Subjects randomized to sipuleucel-T arm will receive 3 infusions of sipuleucel-T at approximately 2-week intervals. Intervention: Biological: sipuleucel-T • No Intervention: Control Arm: Active Surveillance Subjects randomized to the control arm will be followed on Active Surveillance described in the schedule of events.
Recruitment Status	**Active, not recruiting**
Eligibility Criteria	Inclusion Criteria: 1. Age is ≥ 18 years 2. Written informed consent provided prior to the initiation of study procedures 3. Histologically proven adenocarcinoma of the prostate initially diagnosed ≤12 months of Screening. All biopsy slides with subject information redacted must be submitted for BICR. 4. Prostate cancer diagnosis determined by BICR as one of the following: 4a. ISUP Grade Group 1 with 3 or more cores positive from a systematic (≥10 cores) biopsy 4b. ISUP Grade Group 1 with ≥ 1 core positive with ≥50% cancer involvement from a systematic (≥10 cores) biopsy 4c. ISUP Grade Group 1 from 3 or more positive cores from any combination of cores from a systematic (≥10 cores) biopsy and MRI targeted biopsy (note: multiple cores from each MRI targeted lesion will count as 1 core) 4d. ISUP Grade Group 1 from a negative systematic (≥10 cores) biopsy and an MRI targeted core positive with ≥50% cancer involvement 4e. ISUP Grade Group 2 from a systematic (≥10 cores) biopsy with <50% of the total number of any cores positive for cancer 4f.

	ISUP Grade Group 2 from a negative systematic (≥10 cores) biopsy and MRI targeted core(s) positive for Gleason 3+4 (see note below) 4g. ISUP Grade Group 2 from any combination of cores from a systematic (≥10 cores) biopsy and MRI targeted biopsy (see note below) Note for 4f and 4g: the total number of positive cores must be <50% of total cores from both the systematic biopsy and MRI targeted lesions; each MRI targeted lesion, irrespective of multiple positive cores, will each count as 1 core for the total number of positive cores, e.g., 4 targeted lesions with 2 positive cores each will only add 4 to the total core count. 5. Subject consents to standard of care for biopsy frequency of 2 on-study prostate biopsies and to provide biopsy tissue for study endpoint analysis. 6. Estimated life expectancy ≥ 10 years 7. Candidate for primary curative therapy (e.g., surgery or radiation) if prostate cancer progression occurs 8. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 9. Adequate baseline hematologic, renal, and liver function tests as evidenced by laboratory test results within the following ranges ≤30 days prior to randomization White blood cell (WBC) count ≥ 3.0 x 10^6 cells/mL Absolute neutrophil count (ANC) ≥ 1.5 x 10^6 cells/mL Platelet count ≥ 1.0 x10^5 cells/uL Hemoglobin (Hgb) ≥ 10.0 g/dL Creatinine ≤ 1.5 mg/dL Total bilirubin ≤ 1.5 x upper limit of normal (ULN) Alanine aminotransferase (ALT) ≤ 2.0 x ULN Aspartate aminotransferase (AST) ≤ 2.0 x ULN Exclusion Criteria: 1. Former therapy for prostate cancer (local or systemic) 2. Any previous prostatic surgical procedure that significantly changes the anatomy of prostate (at the discretion of sponsor's Medical Monitor) 3. Any investigational product received for prostate cancer 4. Prostate biopsy specimen reveals neuroendocrine or small cell features 5. Primary Gleason score is ≥ 4 or any Gleason pattern 5 6. Any evidence of locally advanced, regional or metastatic disease, including regional and distant lymph node enlargement (Nodes ≥1.5 cm in the short axis are considered pathologic and measurable) 7. A history of a cerebrovascular event (CVE) or transient ischemic attack (TIA) 8. Subject has used a 5-alpha-reductase inhibitor (e.g., finasteride or dutasteride) continuously for ≥ 6 months and within 6 months prior to study Screening 9. Subject has a history of any other stage I-IV malignancy, except for basal or squamous cell skin cancer. The subject must be disease free and off any malignancy-related treatment for at least 5 years. 10. Subject has prior use within 30 days of study Screening of any herbal, dietary, or alternative anti-cancer treatment or product, such as PC-SPES (or PC-x product), saw

	palmetto, ketoconazole, an estrogen-containing nutraceutical, or high dose calcitriol (>0.5 µg/day). The Investigator will consider herbal therapies on a case-by-case basis to determine whether they fall into the category of prohibited medications based on their potential for hormonal or anti-cancer or anti-cancer properties. 11. Need for systemic chronic immunosuppressive therapy (e.g., anti-tumor necrosis factor alpha monoclonal antibodies, glucocorticoids) 12. Uncontrolled, concurrent illness including, but not limited to the following: ongoing or active infection (bacterial, viral, or fungal), symptomatic congestive heart failure (New York Classification III-IV) or unstable angina pectoris within the last 6 months, or psychiatric illness that would limit compliance with study requirements as well as any condition that would preclude a subject from undergoing leukapheresis (e.g., within the previous 6 months: myocardial infarction, interventional cardiology procedure such as angioplasty or stent placement, pulmonary embolism or deep vein thrombosis). 13. Hypogonadal (T <175 ng/dL) or on continuous testosterone replacement therapy 14. Positive serology for HIV-1, HIV-2 or HTLV-1, HTLV-2 15. Active hepatitis B or C 16. Any medical intervention, any other condition, or any other circumstance which, in the opinion of the investigator or the sponsor's Medical Monitor, could compromise adherence with study requirements or otherwise compromise the study's objectives.