Dendreon P23-1 (PROVONE)

Phase II | mCRPC | Provenge® Booster Study

Study Overview

This Phase II, open-label study evaluates whether a **single booster infusion of Provenge® (sipuleucel-T)** given approximately **6 months after standard Provenge treatment** enhances the immune response and improves long-term outcomes in men with **metastatic castration-resistant prostate cancer (mCRPC)**. Patients who complete the standard 3-dose Provenge regimen are randomized 1:1 to receive either a booster infusion or no booster. Primary endpoint is immune response; secondary endpoints include overall survival and safety.

Key Inclusion Criteria

- Male ≥18 years
- Asymptomatic or minimally symptomatic **mCRPC**
- Eligible for and completed **all 3 standard Provenge infusions**
- Life expectancy **≥12 months**
- Able to provide informed consent

Key Exclusion Criteria

- Chronic systemic immunosuppressive therapy
- Uncontrolled infection or significant concurrent illness
- Psychiatric or medical condition preventing study compliance
- Receiving another investigational therapy

Why Consider This Study?

- Evaluates a potential strategy to **boost immune response after Provenge**
- Standard Provenge administered per approved label
- Randomization occurs after completion of Provenge
- Long-term survival follow-up for up to **5 years**