

NCCN Prostate Cancer Guidelines Version 2.2010 – Interim Update Teleconference – 05/19/2010

Guideline Page and Request	Panel Discussion	References	Include in Guideline Votes	
			YES	NO
<p><u>PROS-9</u> Internal request: Panel teleconference request based on the FDA approval of the immunotherapeutic agent sipuleucel-T (Provenge) for the treatment of advanced prostate cancer on April 29, 2010.</p> <p>External request: Submission request from Dendreon Corp. on May 3, 2010.</p>	<p>There are two phase 3 trials published for symptomatic or minimally symptomatic, metastatic castration recurrent prostate cancer. The median survival was 4 mo and a 22 % reduction in risk of death from prostate cancer compared to placebo.</p> <p>The most common adverse effects associated with treatment were primarily grade 1 and 2, with durations of 1-2 days.</p> <p>Based on this data, Panel members supported the inclusion of sipuleucel-T as a treatment option in the guideline.</p> <p>Physicians should not be offering this to patients who are symptomatic after receiving docetaxel.</p>	<p>1. Higano CS, Schellhammer PF, Small EJ, et al. Integrated data from 2 randomized, double-blind, placebo-controlled, phase 3 trials of active cellular immunotherapy with sipuleucel-T in advanced prostate cancer. <i>Cancer</i>. 2009;115:3670-9.</p> <p>2. Small EJ, Schellhammer PF, Higano CS, et al. Placebo-controlled phase 3 trial of immunologic therapy with sipuleucel-T (APC8015) in patients with metastatic, asymptomatic hormone refractory prostate cancer. <i>J Clin Oncol</i>. 2006;24:3089-94.</p> <p>3. http://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM210031.pdf</p>	19	1