UROGPO

National Comprehensive Cancer Network (NCCN) guidelines for treatment of advanced, metastatic prostate cancer. ELEVATING THE ROLE OF PROVENGE ® (sipuleucel-T)

Updated NCCN guidelines validate the use of PROVENGE (sipuleucel-T) **before** enzalutamide, abiraterone, chemotherapy, and other treatments in asymptomatic or minimally symptomatic mCRPC patients

RECOMMEND USE AS FIRST TREATMENT…

with an overall survival advantage for men with asymptomatic or minimally symptomatic mCRPC

Guidelines affirm survival Advantage and tolerability of PROVENGE ® (sipuleucel-T)

- **Extends median survival from 21.7 months in the control group to 25.8 months in the treatment group - a 22% reduction in mortality risk**
- **Cites chills, pyrexia, and headache as common complications**

NCCN also clarifies which patients should be considered for treatment with PROVENGE ® (sipuleucel-T)

- **Good performance status (ECOG 0-1)**
- **Estimated life expectancy >6 months**
- **No hepatic metastases**
- **No or minimal symptoms**
- **Does not require narcotics for cancer-related pain**

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. Closely monitor patients with cardiac or pulmonary conditions.

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.

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.

Handling Precautions: PROVENGE is intended solely for autologous use and is not tested for transmissible infectious diseases.

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.

REFERENCE: National Comprehensive Cancer Network.

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