**INTRODUCTION**

Sipuleucel-T is an autologous cellular immunotherapy that targets prostate acid phosphatase and was approved in the USA in 2009 for the treatment of men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer (mCRPC), and in the EU in 2013 for the treatment of asymptomatic or minimally symptomatic mCRPC (non-metastatic) in men affected by prostate cancer that is not yet clinically evident.1-2

- Approval of sipuleucel-T for mCRPC was based primarily on the randomized, controlled, Phase 3 study (IMP321), which showed that sipuleucel-T treatment was associated with a 25% reduction in the risk of death (hazard ratio [HR] = 0.78; confidence interval [CI]: 0.64-0.95) compared to placebo.

A registry of sipuleucel-T therapy in men with advanced prostate cancer (PROCEED) - PROCEDURE is an ongoing, multicenter, Phase 4 registry in the USA that enrolled patients treated with sipuleucel-T outside of a sipuleucel-T clinical trial. The registry tracks clinical outcomes and includes patients who have been approved for serious adverse events, overall survival (OS), and treatments after sipuleucel-T.

- The primary objective is to further quantify the risk of clinical events in men treated with sipuleucel-T.
- The registry also captures data on product manufacturing parameters and demographic data.

**METHODS**

- Patients who had been prescribed sipuleucel-T or their first subsequent treatments for sipuleucel-T no more than 6 months prior to informed consent, following the last infusion of sipuleucel-T, are included in the study.
- Demographics, disease characteristics, and previous and ongoing anti-cancer treatments are recorded at baseline.
- During follow-up, all prostate cancer therapies administered after sipuleucel-T are recorded.

**Statistical modeling and analysis**

- To date, 1,020 patients were enrolled in PROCEED; as of March 2014, 1,906 patients had received at least one infusion of sipuleucel-T. Of the 1,506 patients, 1,024 (68%) had an anticancer intervention after receiving sipuleucel-T and 470 patients (30%) had received chemotherapy following sipuleucel-T.

**RESULTS**

- The most common anticancer interventions included ablation, endocrine, chemoradiation, palliative care, and symptoms management.
- Chemotherapy interventions were included as the anticancer interventions.
- The most common chemotherapy interventions included docetaxel, cabazitaxel, and carboplatin.

**CONCLUSIONS**

- **PROCEDURE** provides important real-world longitudinal information about the treatment of mCRPC patients with sipuleucel-T.
- Preliminary statistical modeling of time to first anticancer intervention after sipuleucel-T indicates that younger patients, those who had higher baseline alkaline phosphatase values, had higher baseline weight, and those who had higher baseline PSA levels, moved on to anticancer interventions faster.
- Preliminary statistical modeling of time to chemotherapy after sipuleucel-T indicates that patients who are younger, have higher baseline alkaline phosphatase, higher baseline PSA values, or had previously received chemotherapy move on to subsequent chemotherapy treatment sooner.