Protocol Title: Prospective Observational Cohort Study of Patients with Castration-Resistant Prostate Cancer (CRPC) in the United States (TRUMPET)

Target Population: Prostate Cancer
   • Metastatic Prostate Cancer
   • Castration – Resistant Prostate Cancer (CRPC)

Summary: The purpose of this study is to describe patterns of care in CRPC patients, as well as Health-Related Quality of Life (HRQoL) outcomes associated with CRPC and its management. This study will also describe factors influencing treatment decisions including reason(s) for treatment choices and triggers for treatment changes for CRPC as well as describe clinical outcomes based on patient characteristics.

Key Inclusion Criteria:
• Patient may have M0 or M1 disease.
• Confirmed diagnosis of CRPC defined by both Testosterone at Castrate Levels, as evidenced by a Serum Testosterone Level ≤ 1.73 nmol/L (50 ng/dL) and clear progressive disease, as evidenced by a minimum of 2 rising PSA levels measured at least 7 Days apart or new clinical or imaging evidence of progressive metastatic disease.
• Initiating the first-line or second-line treatment for CRPC, including:
  o Anti-Androgens
  o Androgen Synthesis Inhibitors
  o Chemotherapy
  o Immunotherapy
  o Radionuclide Therapy
  o Note: Previous First-Line CRPC Treatments are limited to:
    ▪ First Generation Anti-Androgens (Bicalutamide, Flutamide, or Nilutamide)
    ▪ Sipuleucel-T
• Patients may be enrolled within 90 Days from the time of decision to treat or within 90 Days of treatment initiation.
• Caregiver Inclusion Criteria:
  o Meets the definition of an unpaid relative or friend who helps the patient with his or her activities of daily living.
  o Willing and able to complete caregiver-reported outcome questionnaires over the course of the patient’s participation in the study

Key Exclusion Criteria:
• Receiving concomitant treatment for other cancer within 6 Months prior to enrollment, with the following exceptions:
  o Basal Cell Carcinoma
  o Squamous Cell Carcinoma
  o Treatment for Hormone-Sensitive Prostate Cancer

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For additional information: https://clinicaltrials.gov/ct2/show/NCT02380274