A PROSPECTIVE, MULTINATIONAL OBSERVATIONAL STUDY OF MEN WITH LATER-STAGE PROSTATE CANCER, A NEW GLOBAL STUDY TO EXAMINE PATTERNS OF CARE AND OUTCOMES

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Background: The treatment landscape for men with later-stage prostate cancer has changed dramatically over the past several years due to an increase in the understanding of the natural history of the disease and the availability of multiple new therapies. The influx of new agents has made treatment decisions for clinicians increasingly complex and little is known about how patients are treated in daily clinical practice. We report the initiation of a new observational study designed to provide insight into global treatment trends and outcomes across the treatment continuum for later stage prostate cancer. The findings of this study may inform the design of new interventional studies and the development of global best practices.

Trial design: This is a prospective, multinational, longitudinal, observational study. Men are included if they have been diagnosed with prostate adenocarcinoma, provided written informed consent, belong to one of three patient subsets: (1) biochemical failure and a rapid PSA doubling time following curative-intent treatment; (2) newly diagnosed with castration-resistant disease; or (3) metastatic disease at initial presentation, and will receive active treatment at study entry. Exclusion criteria include prior treatment with systemic chemotherapy, life expectancy of <1 year due to comorbidities, or participation in a clinical trial of investigational therapy at study entry. The primary objective of the study is to describe patterns in disease management and clinical outcomes. The secondary objectives are to identify factors influencing treatment decisions and to document healthcare resource utilization. Patients will be followed for a minimum of 4 years and up to 6 years. Data entry is electronic. Physician and patient confidentiality are strictly maintained. Study Status: Approximately 2,900 patients will be enrolled from 31 countries in the Americas (Latin America, Canada), Europe, Asia Pacific, and Middle East and North Africa. The study was recently opened for recruitment (NCT02066961) and the first few patients have been enrolled. Updated enrollment figures will be provided at the time of presentation.

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