Protocol Title: Phase II-III Trial of Adjuvant Radiotherapy Following Radical Prostatectomy With or Without Adjuvant Docetaxel

Target Population: Stage I, II, or III Prostate Adenocarcinoma

Summary: To assess the benefit of Docetaxel as measured by improvement in freedom from progression (Phase II) and subsequently metastasis free survival (Phase III) when given in combination with radiation and androgen deprivation in treatment of High-Risk Prostate Cancer Post-Radical Prostatectomy.

Key Inclusion Criteria:
- Patients Post-Prostatectomy with baseline Gleason ≥ 7 (per Prostatectomy Pathology) and baseline PSA nadir ≥ 0.2 ng/ml obtained prior to registration.
- Baseline Testosterone Level obtained Post-Prostatectomy prior to registration.
- Pathologically proven diagnosis of Adenocarcinoma of the Prostate as confirmed at time of Prostatectomy.
  - Note: Prostatectomy must have been performed ≤ 365 Days (1 Year) prior to registration.
- Primary treatment with Radical Prostatectomy.
- Any type of Radical Prostatectomy is permitted, including retropubic, perineal, laparoscopic, or robotically assisted.
- Prior ablative treatment for Benign Prostatic Hypertrophy or focal HIFU prior to Prostatectomy is allowed.
- Prior Androgen Deprivation (LHRH Agonist and / or Non-Steroidal Anti-Androgen) is allowed if discontinued at least 90 Days prior to study enrollment and given for ≤ 90 Days duration.
  - Finasteride or Dutasteride must be stopped before treatment but should not determine eligibility.
  - For patients on prior LHRH Analogs, the discontinuation date should be calculated based on the expected duration of the sustained release injection, not simply the injection date of the drug.
- Pathologically proven to be either:
  - Lymph Node Negative by Pelvic Lymphadenectomy (pN0)
  - Lymph Node Status Pathologically Unknown (Undissected Pelvic Lymph Nodes [pNx])
- Any pT-Stage based on AJCC 7th edition is acceptable for study entry based on following diagnostic workup:
  - History/physical examination within 60 Days prior to registration.
  - No distant metastases, based upon the following minimum diagnostic workup:
    - CT Scan of Abdomen and Pelvis or MRI of Pelvis ≤ 120 Days prior registration
      - Lymph Nodes will be non-metastatic unless they measure > 1.5cm short axis.
    - Bone Scan ≤ 120 Days prior to registration.
      - If the Bone Scan is suspicious, X-Ray, CT Scan, NaF PET / CT and / or MRI should be obtained to rule of metastasis.
- Available surgical Formalin-Fixed Paraffin-Embedded (FFPE) Specimen.

Key Exclusion Criteria:
- Definitive clinical or radiologic evidence of metastatic disease.
- Prior radiotherapy to the region of the study cancer that would result in overlap of radiation therapy fields.
- Prior systemic chemotherapy for the study cancer.
  - Prior chemotherapy for a different cancer is allowable if completed > 2 Years prior to registration.
- Prior whole gland ablative therapy (i.e. Cryoablation or HIFU) for Prostate Cancer is allowed.
  - Prior focal HIFU or treatment for Benign Prostatic Hypertrophy is allowed.
- Prostatectomy performed > 365 Days (1 Year) prior to registration.

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For additional information: https://clinicaltrials.gov/ct2/show/NCT03070886

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