Testing the Addition of the Drug Relugolix to the Usual Radiation Therapy for Advanced-Stage Prostate Cancer, The NRG Promethean Study

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Pathologically (histologically or cytologically) proven diagnosis of prostate adenocarcinoma at any anatomical location (for example, prostate, metastatic site), including intraductal or ductal carcinoma, at any time before registration * Age \>= 18 years * Eastern Cooperative Oncology Group (ECOG) performance status 0-2 within 180 days prior to registration * Prior curative-intent treatment to the prostate, by either: * External beam and/or brachytherapy to: Prostate alone, prostate and seminal vesicles, prostate and pelvic nodes, or radiation to all three sites * Radical prostatectomy alone, radical prostatectomy plus postoperative radiotherapy to the prostate bed, or radical prostatectomy plus postoperative radiotherapy to the pelvic nodes. * Note: Patients who have received curative intent with radiation prior to prostatectomy are eligible and should be categorized as RT to Intact Prostate since that was the first curative intent * Must meet study entry criteria based on the following diagnostic workup within 120 days prior to registration: * History and physical examination; * Fluciclovine or PSMA PET scan; * PET must be combined with either CT or MRI, but a diagnostic CT or MRI reading/interpretation is not required * 1

•5 oligometastatic lesions in bone and/or nodal/soft tissue (non-abutting nodes are counted separately) sites on fluciclovine or PSMA PET within 180 days prior to registration and includes at least ONE of the following: * Bone

•each metastasis is counted (for example, 2 distinct lesions in the right ilium count as 2 oligometastatic lesions) * Extrapelvic Nodal/ soft tissue

•requires at least one extrapelvic inguinal or a nodal/soft tissue lesion superior to the iliac bifurcation (that is, American Joint Committee on Cancer \[AJCC\] M1a version 8) * Note: Although a patient must have bone and/or extrapelvic disease to be eligible, when counting the number of oligometastatic lesions, each lymph node lesion, whether pelvic or extrapelvic, is counted (for example, 2 distinct lymph nodes in the right external iliac basin count as 2 oligometastatic lesions; one extrapelvic and one pelvic node count as 2 oligometastic lesions, etc) * Serum total prostate-specific antigen (PSA) =\< 10.0 ng/mL that also meets ONE of the following PSA recurrence definitions: * If patient has received-radiation therapy to intact prostate, either * PSA \> post-RT nadir PSA + 2 ng/mL obtained within 180 days prior to registration, or * PSA \> 0.2 ng/mL with at least two rises from post-treatment nadir with the most recent PSA within 180 days prior to registration * If patient has received a radical prostatectomy with or without post-op RT, either * Current PSA \> 0.2 ng/mL, with a second confirmatory PSA \> 0.2 ng/mL, with most recent PSA obtained within 180 days prior to registration, or * Two consecutive PSA rises from post-operative nadir, with most recent PSA obtained within 180 days prior to registration * Must have \>= 3 PSA values within the last two years since end of primary treatment or within the last 2 years prior to registration, whichever is less * Note: PSA doubling time must be calculated by entering all PSA values since end of primary treatment or within the last 2 years prior to registration (whichever is less) into the PSA Doubling Time Calculator found at MDCalc.com * Serum total testosterone \>= 100 ng/dL within 180 days prior to registration * Note: Prior androgen deprivation therapy (other than bilateral orchiectomy) is allowed if discontinued prior to registration and serum total testosterone is \>= 100 ng/dL * Total bilirubin: =\< 1.5 x institutional upper limit of normal (ULN) (Note: In subjects with Gilbert's syndrome, if total bilirubin is \> 1.5 x ULN, subject is eligible if direct bilirubin is =\< 1.5 x ULN) (within 180 days prior to registration) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \[SGOT\]) and alanine aminotransferase (ALT) (serum glutamic pyruvic transaminase \[SGPT\]): =\< 2.5 x institutional ULN (within 180 days prior to registration) * For patients with evidence of chronic hepatitis B virus (HBV) infection, the HBV viral load must be undetectable on suppressive therapy, if indicated * Note: Known positive test for hepatitis B virus surface antigen (HBV sAg) indicating acute or chronic infection would make the patient ineligible unless the viral load becomes undetectable on suppressive therapy. Patients who are immune to hepatitis B (anti-hepatitis B surface antibody positive) are eligible (e.g. patients immunized against hepatitis B) * Patients with a history of hepatitis C virus (HCV) infection must have been treated and cured. For patients with HCV infection who are currently on treatment, they are eligible if they have an undetectable HCV viral load * Note: Known positive test for hepatitis C virus ribonucleic acid (HCV RNA) indicating acute or chronic infection would make the patient ineligible unless the viral load becomes undetectable on suppressive therapy * Human immunodeficiency virus (HIV)-infected patients on effective anti-retroviral therapy with undetectable viral load within 6 months are eligible for this trial * The patient must agree to use a highly effective contraception (even men with vasectomies) if he is having sex with a woman of childbearing potential or with a woman who is pregnant while on study drug and for 2 weeks following the last dose of study drug * The patient or a legally authorized representative must provide study-specific informed consent prior to study entry and, for patients treated in the United States (U.S.), authorization permitting release of personal health information

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Exclusion Criteria:

* Currently on androgen deprivation or anti-androgen therapy * Spinal cord compression, or spinal intramedullary, brain, and/or visceral (for example liver, etc.) metastasis * Note: Spinal metastases (PET-detected) with epidural extension are eligible if there is \> 0.3 cm spatial separation between the gross tumor volume and spinal cord. Lung metastases are eligible * Biopsy-proven prostatic carcinoma with signet-ring, sarcomatoid, or neuroendocrine features (for example, small cell) * Prior metastatic or non-metastatic, invasive malignancy (except non metastatic, non-melanomatous skin cancer) unless continuously disease free for \>= 3 years * Prior chemotherapy for prostate cancer or bilateral orchiectomy * Note: Prior chemotherapy for a different cancer is allowed if continuously disease-free for \>= 3 years * Prior high dose radiotherapy to a lesion (i.e. oligometastatic recurrence by PET) * Note: Lesions included in or near a previously irradiated planning target volume (PTV) are eligible as long as previous delivered dose is estimated to be less than an EQD2 of 50 Gy * Inability to treat all oligometastatic sites with radiotherapy in the judgement of the investigator * Intrapelvic lymph nodes as only site of prostate cancer recurrence * Inability to swallow whole, undivided, unchewed, and uncrushed pills * Known gastrointestinal disorder affecting oral medication absorption * Co-morbidity defined as follows: * Patients with any comorbidities that would prohibit completion of protocol specified therapy * Inflammatory bowel disease in patients in whom abdominopelvic radiotherapy is planned * History of congenital long QT syndrome * Current severe or unstable angina * New York Heart Association functional classification III/IV heart failure (Note: Patients with known history or current symptoms of cardiac disease, or history of treatment with cardiotoxic agents, should have a clinical risk assessment of cardiac function using the New York Heart Association functional classification)

Conditions & Interventions

Interventions:

PROCEDURE: Biospecimen Collection, PROCEDURE: Bone Scan, PROCEDURE: Computed Tomography, OTHER: Fluciclovine F18, PROCEDURE: Magnetic Resonance Imaging, DRUG: Placebo Administration, PROCEDURE: Positron Emission Tomography, PROCEDURE: PSMA PET Scan, DRUG: Relugolix, RADIATION: Stereotactic Body Radiation Therapy

Conditions:

Oligometastatic Prostate Carcinoma, Prostate Adenocarcinoma, Prostate Ductal Adenocarcinoma, Prostate Intraductal Carcinoma, Stage IVB Prostate Cancer AJCC v8

More Information

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