

FAST FACTS

S1802 - PHASE III RANDOMIZED TRIAL OF STANDARD SYSTEMIC THERAPY (SST) VERSUS STANDARD SYSTEMIC THERAPY PLUS DEFINITIVE TREATMENT (SURGERY OR RADIATION) OF THE PRIMARY TUMOR IN METASTATIC PROSTATE CANCER

ELIGIBILITY CRITERIA

STEP 1 REGISTRATION

Disease-Related Criteria

1. All patients must have a histologically or cytologically proven diagnosis of adenocarcinoma of the prostate. Patients with pure small cell carcinoma* (SCC), sarcomatoid, or squamous cell carcinoma are not eligible. (*morphology must be consistent with SCC; synaptophysin or chromogranin positive by immunohistochemical staining is insufficient to diagnose SCC).
2. Patients must have an intact prostate.
3. Patients must have at least one of the following scans performed, showing evidence of metastatic disease:
 - technetium bone scan OR
 - CT of abdomen & pelvis OR
 - MRI of pelvis.The scan showing metastases must be performed in the range of 42 days before and 14 days following the start of first hormonal therapy. Metastatic disease that is detected by PET scan only (NaF, PSMA, FACBC, C11) but not conventional imaging (Tc99 bone scan, CT or MRI) or solitary metastases by conventional imaging, must be confirmed histologically or cytologically.
4. Patients with known brain metastases are not eligible. Brain imaging studies are not required for eligibility if the patient has no neurologic signs or symptoms suggestive of brain metastasis. If brain imaging studies are performed, they must be negative for disease.

Prior/Concurrent Therapy Criteria

1. Patients must have received no more than 28 weeks of SST, as measured from the date of first hormonal therapy (LHRH agonist or LHRH antagonist) or surgical castration. SST is defined as current NCCN guidelines for metastatic prostate cancer.
2. No prior local therapy for prostate adenocarcinoma is allowed (e.g., brachytherapy, HIFU, cryotherapy, laser ablative therapies). Any prior therapy for benign conditions, such as obstruction, are acceptable (e.g., transurethral resection of the prostate, greenlight laser ablation, microwave ablation).
3. Patients must not have received any prior systemic therapy for prostate cancer, outside of line of SST to be used for duration of study.
4. Patients must not have progressed while on SST (see Section 10.0).
5. Patients with oligometastatic prostate cancer may receive metastasis directed therapy to up to four sites of disease prior to randomization. Acceptable approaches are included in Section 7.0.

Clinical/Laboratory Criteria

1. Patients must be ≥ 18 years of age.
2. Patients must have a complete physical examination and medical history within 28 days prior to registration.
3. Patients must have a PSA documented prior to initiation of SST and within 28 days prior to registration. Any additional PSAs measured while receiving SST should be recorded.
4. No other prior malignancy is allowed except for the following: adequately treated basal cell or squamous cell skin cancer, adequately treated Stage 0, I or II cancer from which the patient is currently in complete remission, or any other cancer from which the patient has been disease free for three years.

Specimen Submission Criteria

1. Patients must be offered the opportunity to participate in translational medicine studies and specimen banking for future studies as outlined in [Section 15.0](#).

Quality of Life Criteria

1. Patients who can complete Patient-Reported Outcome instruments in English, Spanish or French, must participate in the quality of life studies.

STEP 2 RANDOMIZATION**Disease-Related Criteria**

1. Patients must have no evidence of disease progression (see Section 10.0) during the 28 weeks of SST, as shown by:
 - PSA measure
 - imaging (bone scan and one of the following: CT of abdomen & pelvis, MRI of abdomen & pelvis, CT of abdomen & MRI of pelvis) within 42 days prior to randomization.
2. Patients must have no evidence of symptomatic deterioration (as defined by physician discretion) within 28 days prior to randomization.
3. Patients must have consultation with a urologist and have surgically resectable disease regardless of definitive treatment intent or randomization.

Prior/Concurrent Therapy Criteria

1. Patients must have received at least 22 and no more than 28 weeks of SST, as measured from the date of first hormonal therapy (LHRH agonist or LHRH antagonist) or surgical castration. SST is defined by current NCCN guidelines for metastatic prostate cancer (see Section 7.0).
2. Patients must not be planning to receive docetaxel after randomization.
3. All SST-related toxicities must have resolved to \leq Grade 1 (CTCAE Version 5.0) except for fatigue, weight gain, and hot flashes prior to randomization.
4. Patients may have received elective metastasis directed therapy to oligometastatic sites (≤ 4 sites). All treatment must be completed prior to randomization. (see [Section 7.0](#)).

Clinical/Laboratory Criteria

1. Patients must have a PSA performed within 28 days prior to randomization.
2. Patients must have a testosterone < 50 ng/dL within 28 days prior to randomization.
3. Patients must have a Zubrod performance status of 0 – 1 within 28 days prior to randomization (see [Section 10.5](#)).

