Cancer Research Consortium of West Michigan
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# 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 participants must have a histologically or cytologically proven diagnosis of adenocarcinoma of the prostate. Participants 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. **Participants must have an intact prostate.**

3. **Participants 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 or 14 days following the start of SST. The start date of SST is considered the date of first hormonal therapy (LHRH agonist or LHRH antagonist) or surgical castration. 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, unless the CT portion of the PET scan shows evidence clearly positive for metastatic disease and is also not a solitary lesion.**

4. **Participants with known brain metastases are not eligible. Brain imaging studies are not required for eligibility if the participant has no neurologic signs or symptoms suggestive of brain metastasis. If brain imaging studies are performed, they must be negative for disease.**

b. **Prior/Concurrent Therapy Criteria**

1. **Participants 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. **Participants must not have received any prior systemic therapy for prostate cancer, outside of line of SST to be used for duration of study.**

4. **Participants must not have progressed while on SST (see Section 10.0).**

**5. Participants 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. **Participants must be ≥ 18 years of age.**

2. **Participants must have a complete physical examination and medical history within 28 days prior to registration.**

3. **Participants must have a documented PSA:**
   - **Prior to initiation of SST**
   - **Within 52 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 participant is currently in complete remission, or any other cancer from which the participant has been disease free for three years.**

**Specimen Submission Criteria**

5. **Participants 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**

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

**Regulatory Criteria**

7. **Participants must be informed of the investigational nature of this study and must sign and give written informed consent in accordance with institutional and federal guidelines.**

8. **As a part of the OPEN registration process (see Section 13.3 for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.**

**STEP 2 RANDOMIZATION**

**Disease-Related Criteria**

1. **Participants 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. **Participants must have no evidence of symptomatic deterioration (as defined by physician discretion) within 28 days prior to randomization.**

3. **Participants case must have been reviewed with a urologist and have surgically resectable disease regardless of definitive treatment intent or randomization.**

**Prior/Concurrent Therapy Criteria**

1. **Participants 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. **Participants must not be planning to receive docetaxel after randomization.**

3. **All SST-related toxicities must have resolved to ≤ Grade 1 (CTCAE Version 5.0) except for fatigue, weight gain, and hot flashes, prior to randomization.**

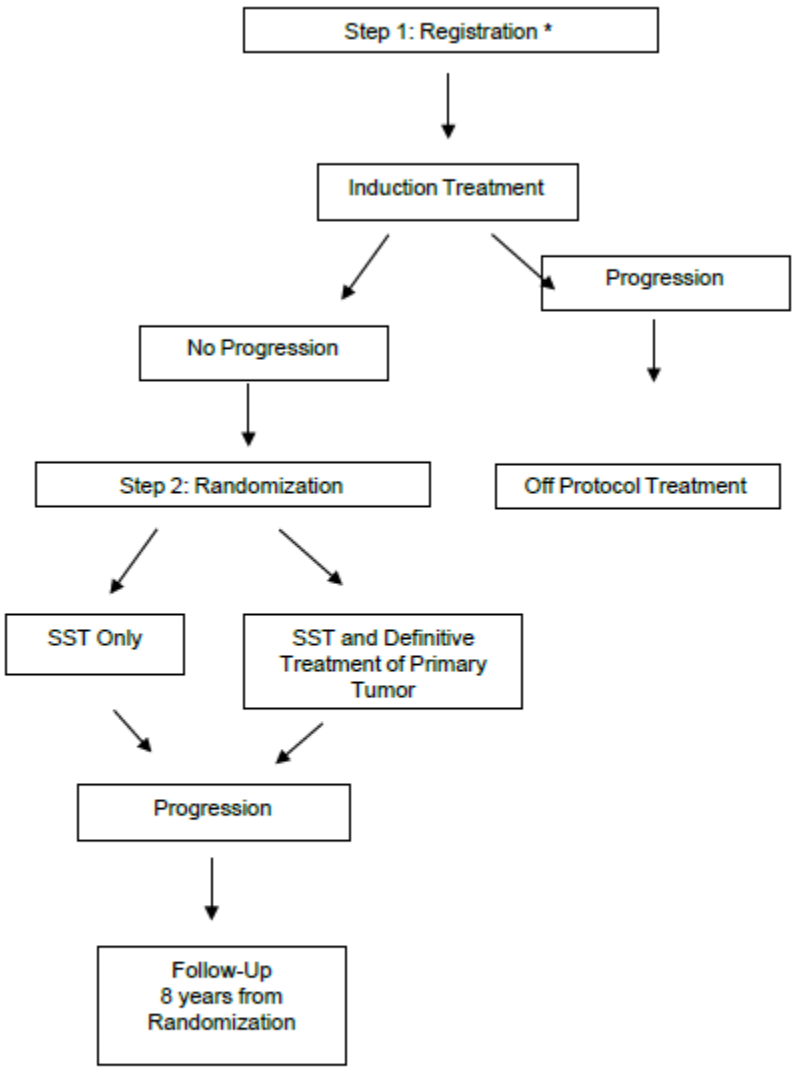
4. **Participants may have received elective metastasis directed therapy to oligometastatic sites (≤4 sites). All treatment must be completed prior to randomization. (see Section 7.0).**

**Clinical/Laboratory Criteria**

5. **Participants must have a PSA performed within 28 days prior to randomization.**

6. **Participants must have a Zubrod performance status of 0 – 1 within 28 days prior to randomization (see Section 10.5).**

**SCHEMA**




* Step 1 registration can occur prior to start of SST or up to 28 weeks after start.