The NCCN Oncology Research Program (ORP) strives to improve the quality of life for patients and reduce cancer-related deaths by advancing cancer therapies through research. Since the program's establishment in 1999, the NCCN ORP has brought millions of dollars in research grants to investigators at NCCN Member Institutions. Research grants are provided to NCCN through collaborations with pharmaceutical and biotechnology companies; these grants are in turn used to support scientifically meritorious cancer research efforts.

NCCN ORP studies typically explore new avenues of clinical investigation and seek answers to important cancer-related questions. All studies are approved and funded through a scientific peer-review process and are overseen by the ORP.

This feature highlights an NCCN study funded through the grant mechanism.

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For more information on specific trials, including patient selection criteria, use the contact information listed with each study.

For more information on the NCCN ORP, including a complete detailing of the clinical studies currently underway at NCCN Member Institutions, go to www.NCCN.org/clinical_trials/clinicians.asp.

A Phase II Study With a Limited Safety Lead-In of Enzalutamide in Combination With Carboplatin and Paclitaxel in Advanced or Recurrent Endometrioid Endometrial Cancer

Principal Investigator: Shannon Westin, MD, MPH
Condition: Endometrial cancer
Institution: The University of Texas MD Anderson Cancer Center

This is a single-arm, open-label phase II study with a limited safety lead-in of the novel androgen receptor (AR) inhibitor enzalutamide in combination with paclitaxel and carboplatin in previously untreated patients with advanced and recurrent endometrioid endometrial cancer. In the safety lead-in (Part A), 6 patients will be treated with the combination of enzalutamide and standard intravenous carboplatin and paclitaxel. Patients on the phase II portion of study (Part B) will undergo induction treatment with single-agent enzalutamide at 160 mg daily orally for 28 days (cycle 0). Biopsies will be obtained pretreatment and 26 to 28 days after treatment initiation. After the posttreatment biopsy and within 3 to 5 days of completing cycle 0, patients will be initiated on combination therapy of enzalutamide, paclitaxel, and carboplatin.

Primary Objectives:

- Determine clinical activity of combination enzalutamide, carboplatin, and paclitaxel represented as:
  - Objective tumor response (complete response + partial response)
  - Proportion of patients who survive progression-free for at least 6 months after initiating therapy
- Quantify protein and phosphoprotein expression of AR and AR-response genes following enzalutamide treatment in match-paired pretreatment and posttreatment tumor biopsies
- Determine the safety and feasibility of daily enzalutamide given in combination with carboplatin and paclitaxel in women with advanced or recurrent endometrial cancer

Secondary Objectives:

- Determine median response duration
- Estimate progression-free and overall survival
- Evaluate for presence of pharmacokinetic interaction between enzalutamide and paclitaxel

Exploratory Objectives:

- Correlate molecular results, including AR expression and activation, to clinical endpoints
- Identify potential agents to synergize with enzalutamide based on pathways activated after enzalutamide treatment

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