Cancer Research Consortium of West Michigan
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FAST FACTS

NRG-GY033: A PHASE II STUDY OF ANDROGEN RECEPTOR (AR) INHIBITION BY DAROLUTAMIDE IN COMBINATION WITH LEUPROLIDE ACETATE AND EXEMESTANE IN RECURRENT ADULT-TYPE OVARIAN GRANULOSA CELL TUMOR

ELIGIBILITY CRITERIA

- A patient cannot be considered eligible for this study unless ALL of the following conditions are met.
- Submission of tissue is required. Investigators should check with their pathology department regarding release of tissue before approaching patients about participation in the trial (see Section 10 for details).

1.1 Histologically confirmed diagnosis of recurrent adult-type granulosa cell tumor.

1.2 Patient must have measurable disease. Measurable disease is defined in the protocol per RECIST 1.1 criteria. Measurable disease is defined as at least one lesion that can be accurately measured in at least one dimension (longest diameter to be recorded). Each lesion must be ≥ 10 mm when measured by CT or MRI. Lymph nodes must be ≥ 15 mm in short axis when measured by CT or MRI.

1.3 Patient must have had ≥1 treatment regimen

1.4 Subject must have progressed on an aromatase inhibitor (letrozole, exemestane, anastrozole) in a prior treatment line.

1.5 Age ≥ 18 years

1.6 ECOG Performance Status of ≤ 2 (see Appendix I).

1.7 Not Pregnant and Not Nursing

1.8 Adequate hematologic function defined as follows:
- Absolute neutrophil count (ANC) ≥ 1,500 cells/mm3
- Platelets ≥ 100,000 cells/mm3
- Hemoglobin ≥ 8 g/dl (08-DEC-2023)

1.9 Adequate renal function defined as follows:
- Creatinine clearance (CrCL) of ≥30 mL/min by the Cockcroft-Gault formula:

$$\textbf{CrCl (mL/min)} = \frac{\textbf{[140 – age (years)] x weight (kg)}}{\textbf{72 x creatinine (mg/dL)}} \textbf{ \{x 0.85 for female patients\}}$$

1.10 Adequate hepatic function defined as follows:
- Total bilirubin ≤ 1.5 x institutional upper limit of normal (ULN) (patients with known Gilbert's disease who have bilirubin level ≤ 3 x ULN may be enrolled)
- AST and ALT ≤ 1.5 x institutional ULN

1.11 Adequate cardiac function defined as follows:
- 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. *To be eligible for this trial, patients should be class 2B or better (See Appendix II)*

1.12 Comorbid conditions
- No active infection requiring parenteral antibiotics;
- No current evidence of intra-abdominal abscess, abdominal/pelvic fistula (not diverted), gastrointestinal perforation, GI obstruction, and/or need for drainage nasogastric or gastrostomy tube

1.13 The patient or a legally authorized representative must provide study-specific informed consent prior to study entry and, for patients treated in the U.S., authorization permitting release of personal health information.

Ineligibility Criteria

- **Patients with any of the following conditions are NOT eligible for this study.**

2.1 Prior treatment with AR inhibitors

2.2 Known hypersensitivity to the study drugs or their ingredients.