ATLAS

RUCAPARIB IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA

A Phase 2, Open-label Study of Rucaparib in Patients with Locally Advanced or Metastatic Urothelial Carcinoma

ATLAS TRIAL SCHEMA

KEY ELIGIBILITY

- Relapsed metastatic urothelial carcinoma
- 1-2 prior standard of care treatment regimens
- Mandatory biopsy at screening
- Measurable disease
- No prior treatment with any PARP inhibitor
- No selection based on HRD status

TREATMENT

Rucaparib 600 mg BID
(N~200 patients)

Treatment Assessments:

- Rucaparib 600 mg BID until disease progression as assessed by investigator or treatment discontinuation for other reason
- Tumor assessment by CT/MRI every 8 weeks up to 18 months, then every 12 weeks

Long-Term Follow-up

- Tumor assessments every 8-12 weeks for patients who discontinue for reason other than progression
- All patients to be followed every 12 weeks for survival, subsequent therapies, and development of secondary malignancies

STUDY ENDPOINTS

PRIMARY ENDPOINT

- Objective response rate (ORR) in homologous recombination deficiency (HRD) and Intent-to-Treat populations

SECONDARY ENDPOINTS

- Duration of response (DOR)
- Progression-free survival (PFS)
- Overall survival (OS)
- Safety and tolerability
- Pharmacokinetics

Rucaparib has not been demonstrated to be safe or effective, nor has it been approved by any regulatory authority, including the US Food and Drug Administration (FDA), for use in this disease indication

BID = twice daily; ORR = objective response rate; HRD = homologous recombination deficiency; PARP = poly (ADP-ribose) polymerase; PARPi = poly (ADP-ribose) polymerase inhibitor

Please visit www.ClinicalTrials.gov for more information on this trial

ATLAS (NCT03397394) is sponsored by Clovis Oncology, Inc., Boulder, CO, USA

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NP-RUCA-US-0104 01/18