A Basket Trial Evaluating The Safety and Efficacy of Lerapolturev Alone and Lerapolturev in Combination With Anti-PD-1/L1 Checkpoint Inhibitors in Patients With Advanced Solid Tumors

istari ONCOLOGY

LUMINOS-103

Trial Information

Participating Study Centers

Duke University Medical Center, Duke Cancer Center, Durham, NC
New York University Langone Health, New York, NY
University of North Carolina Lineberger Cancer Center, Chapel Hill, NC
University of California San Francisco Medical Center, San Francisco, CA
Carolina Urologic Research Center, Myrtle Beach, SC
Henry Ford Health System, Detroit, MI

Trial Registration Number: NCT04690699
Start Date: June 2021
Estimated Completion Date: June 2025

Objectives

Primary objectives[a]:
- Evaluate safety and tolerability
- Evaluate anti-tumor response (phase 2 only)

Secondary objectives[a]:
- Evaluate anti-tumor response
- Assess viral shedding and immune response

[a]*Unless specified, all objectives are for both phase 1 and 2.*

Key Eligibility Criteria

- ≥18 Age ≥ 18 years
- ECOG PS 0 or 1
- FFPE tumor specimen from archival or fresh biopsy
- Measurable lesion (per RECIST v1.1) amenable to injection
- Vaccination against PV and booster immunization within 1 to 6 weeks of first lerapolturev dose
- No CNS metastases requiring radiation or steroid treatment within 2 weeks of first lerapolturev dose[a]
- No systemic immunosuppressives, major surgeries, or live vaccines within 4 weeks of first lerapolturev dose, and no radio, chemo, immuno, biological, investigational, or hormonal therapies within 3 weeks of first lerapolturev dose[b]

[a]*Leptomeningeal disease is excluded.* [b]*Exceptions allowed for immunosuppressive therapy and adjuvant hormonal therapy for breast or prostate.*

LUMINOS-103 Study Design

LUMINOS-103 — *Solid Tumor Cancer of Interest[a]*

[a]*Detailed schedule of assessments will be provided in each solid tumor specific appendix.*

Phase 1: Safety Run-In Lerapolturev
(n=6 to 18)

≥6 patients with the solid tumor of interest enrolled to assess frequency of DLTs after lerapolturev monotherapy

DSMC Review of Safety Data

Phase 2: Lerapolturev + anti-PD-1/L1
(n≈50)

Lerapolturev + anti-PD-1/L1 therapy initiates after lerapolturev monotherapy dosing regimen is established in phase 1 and is considered safe to proceed by DSMC

Study Endpoints[a]

Primary endpoints:
- AEs, AESIs
- Number of lerapolturev injections received
- ORR per RECIST v1.1 (phase 2 only)

Secondary endpoints:
- ORR (phase 1 only); OS and PFS, DOR, CBR per RECIST v1.1 (phase 1 and 2)
- Stool PV titers
- Assessment of changes from baseline in immune function and tumor biomarkers

Exploratory endpoints:
- Assessment of genetic, cytologic, histologic, and/or other biomarkers
- ORR, DOR, CBR per itRECIST

[a]*Unless specified, all endpoints are for both phase 1 and 2.*

AE, adverse event; AESI, adverse event of special interest; CBR, clinical benefit rate; CNS, central nervous system; CTCAE, Common Terminology Criteria for Adverse Events; DOR, duration of response; DSMC, data safety monitoring committee; ECOG, Eastern Cooperative Oncology Group; FFPE, formalin-fixed paraffin-embedded; itRECIST, intratumoral immunotherapy Response Evaluation Criteria in Solid Tumors; NCI, National Cancer Institute; ORR, overall response rate; OS, overall survival; PD-1, programmed death receptor-1; PD-L1, programmed death-ligand 1; PFS, progression-free survival; PS, performance status; PV, poliovirus; RECIST, Response Evaluation Criteria in Solid Tumors.

For more information, email LUMINOS-103@istarioncology.com **or visit** https://clinicaltrials.gov/ct2/show/NCT04690699.