Istari Oncology Announces First Patient Dosed in the Non-Muscle-Invasive Bladder Cancer (NMIBC) Substudy of the LUMINOS-103 Basket Trial Evaluating Lerapolturev Monotherapy

DURHAM, NC, January 31, 2023 – Istari Oncology, Inc., a clinical-stage biotechnology company focused on development of the novel immune activator lerapolturev for the treatment of solid tumors, today announced the first patient has been dosed via intravesicular instillation in the non-muscle-invasive bladder cancer (NMIBC) cohort of the LUMINOS-103 basket trial. LUMINOS-103 is a dynamic phase 1/2 open-label basket trial evaluating the administration of lerapolturev with or without PD-1/L1 inhibitors in adult subjects with solid cancers.

"We know that NMIBC tissue expresses the poliovirus receptor, CD155 and is responsive to immunotherapy, providing the rationale for intravesicular lerapolturev for patients with low to intermediate risk BCG-naïve NMIBC," said W. Garrett Nichols, MD, MS, Chief Medical Officer at Istari Oncology. "Approximately 60,000 patients with low to intermediate risk NIMBC are identified each year in the US alone; these patients could benefit from a well-tolerated immunotherapy such as lerapolturev as a replacement for repeat resections and intravesicular chemotherapy."

This substudy is designed to test the intravesical instillation of lerapolturev and its ability to infect tumor cells and infiltrating APCs within tumor tissue lining the bladder mucosa.
To facilitate efficient enrollment, a heterogenous population of patients is being recruited (prior history of stage Ta, T1, or Tis urothelial carcinoma of the bladder; recurrent disease requiring TURBT or cystectomy). If successful, the planned patient population for phase 2 will be patients with low- to intermediate-risk BCG-naïve disease.

"We're pleased to be the exclusive site for the NMIBC sub-study," said Dr. Neal Shore principal investigator and Director, Carolina Urologic Research Center. "This is a largely unaddressed population of NMIBC patients that, if we can identify and intervene early and effectively with a therapy like lerapolturev, can avoid progression and repeated surgeries or treatment with BCG, which has experienced severe shortages."

Recruiting for the NMIBC substudy is ongoing and is expected to reach full enrollment by mid-year.

For more information about Istari Oncology and their ongoing clinical trials, visit www.istarioncology.com.

About Lerapolturev
Lerapolturev is an investigational immunotherapy based on the live attenuated Sabin type 1 polio vaccine genetically modified for safety. Lerapolturev has a distinct target (the poliovirus

receptor CD155), which is widely expressed in neoplastic cells of most solid tumors. Via CD155, Lerapolturev targets tumors with three key mechanisms: 1) engagement and activation of antigen presenting cells (APCs), leading to T cell priming and sustained, systemic anticancer immunity; 2) direct tumor cell killing and antigen release; and 3) amplification of the immune response via recall of polio vaccine-specific T cells. Lerapolturev has been granted Breakthrough Therapy and Orphan Drug Designation status by the U.S. Food and Drug Administration in recurrent glioblastoma, and Fast Track and Orphan Drug Designation status in refractory melanoma.

About Istari Oncology

Istari Oncology, Inc., headquartered in Research Triangle Park, North Carolina, is a privately held clinical-stage biotechnology company focused on development of the novel immune activator lerapolturev for the treatment of solid tumors. Istari has licensed a broad range of patents and patent applications and has access to additional intellectual property to continue clinical and commercial development of lerapolturev.

For more information, please visit: www.istarioncology.com.

###

Istari Oncology Medical Affairs Contact:
Email: MedicalAffairs@istarioncology.com

Investor and Media Contact:
John Higgins
Email: jhiggins@istarioncology.com