# Istari Oncology Announces FDA Clearance of New IND to Open LUMINOS-102: PVSRIPO with and without Immune Checkpoint Blockade in Advanced PD-1 Refractory Melanoma

*Phase 2 clinical study expected to begin in First Quarter 2021*

DURHAM, NC, November 16, 2020 – Istari Oncology, Inc., a clinical-stage biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug application (IND) for a Phase 2 clinical trial, LUMINOS-102, to investigate the efficacy and safety of PVSRIPO alone or in combination with a programmed death receptor-1 (anti-PD-1) inhibitor in patients with treatment-refractory melanoma.

PVSRIPO is a novel viral immunotherapy that activates a patient's innate and adaptive immunity to facilitate a targeted anti-tumor immune response. Following positive Phase 1 results in patients with unresectable and/or metastatic melanoma, the new IND will enable continued development of PVSRIPO for advanced melanoma. LUMINOS-102 (NCT04577807) will assess PVSRIPO's impact on patients who have failed anti-PD-1 therapy.

"There is a massive need for treatments targeted at patients who experience primary or acquired resistance to anti-PD-1 therapies," said W. Garrett Nichols, MD, MS, Chief Medical Officer at Istari Oncology. "PVSRIPO has shown promise in treating patients that have failed primary treatment options across multiple solid tumor types. We look forward to building on the positive results of our initial Phase 1 trial in melanoma with LUMINOS 102."

Following a safety run-in, approximately 50 participants with cutaneous or mucosal melanoma who previously failed anti-PD-1 blockade will be randomized 1:1 to receive either PVSRIPO or PVSRIPO plus an anti-PD-1.

Site initiation activities are underway for this Phase 2 trial, which the Company anticipates will begin in the first quarter of 2021. An interim analysis is planned once 20 patients have been randomized and treated for 3 months. Patient outcomes, including objective response rates (by RESICST criteria), durability of responses, and overall survival will be measured over a 24-month time frame.

In a Phase 1 study of PVSRIPO monotherapy in anti-PD1 refractory advanced melanoma presented by Dr. Georgia Beasley and colleagues at the Society for Immunotherapy of Cancer (SITC) 2020 Annual Meeting last week, the overall response rate in subjects who received three single intralesional injections three weeks apart (maximum number administered in the study) was 67% (4/6), suggesting that PVSRIPO was able to initiate or rekindle responses in patients who have failed anti-PD-1 therapy. Responses were observed in both injected and uninjected

tumors (e.g. an abscopal response). No serious adverse events or dose limiting toxicities were observed.

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

**About PVSRIPO**
PVSRIPO is a virus based on the live attenuated Sabin type 1 polio vaccine that has been genetically modified for safety. Unlike other viral immunotherapies, PVSRIPO has a distinct target (the poliovirus receptor CD155), which is widely expressed in neoplastic cells of most solid tumors. Via CD155, PVSRIPO targets tumors with two primary mechanisms: 1) direct damage to and killing of cancerous cells; and 2) engaging innate and adaptive antitumor immune responses via sublethal infection of antigen presenting cells in the tumor, which unleash an inflammatory cascade resulting in sustained systemic antitumor immunity. PVSRIPO has been granted Breakthrough Therapy Designation and Orphan Status by the FDA in recurrent glioblastoma.

**About Melanoma**
There are estimated to be over 12,000 new and recurrent cases of advanced, unresectable melanoma diagnosed in the U.S. each year, and around 7,000 deaths. While immune checkpoint inhibitors have dramatically improved the outlook for advanced melanoma patients today, most patients treated with these immunotherapies are either primary non-responders or eventually develop immune-refractory progressive disease and require additional therapy.

**About Istari Oncology**
Istari Oncology, Inc., headquartered in Research Triangle Park, North Carolina, is a privately held clinical-stage biotechnology company focused on novel immuno-oncology and immunotherapy platforms for the treatment of glioblastoma and a wide variety of tumors. The company was founded by Darell Bigner, MD, PhD and Matthias Gromeier, MD, of Duke University Medical Center in 2016. Istari licensed a broad range of patents and patent applications from Duke University and has access to additional intellectual property to continue clinical and commercial development of these technologies. The company's primary platform currently in clinical development is PVSRIPO. For more information, please visit: www.istarioncology.com.

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