Istari Oncology Announces First Patient Dosed in the LUMINOS-101 Phase 2 Clinical Trial of PVSRIPO in Combination with Pembrolizumab for Patients with Recurrent Glioblastoma

DURHAM, NC, November 30, 2020 – Istari Oncology, Inc., a clinical-stage biotechnology company, today announced the first patient was dosed in the LUMINOS-101 Phase 2 clinical trial, assessing the safety and efficacy of PVSRIPO in combination with the immune checkpoint inhibitor pembrolizumab (Keytruda®) in patients with recurrent glioblastoma multiforme (rGBM).

PVSRIPO is a novel viral immunotherapy that activates a patient's innate and adaptive immunity to facilitate a targeted anti-tumor immune response. The study seeks to determine whether PVSRIPO and pembrolizumab will be able to generate anti-tumor response in patients with rGBM, given their complimentary mechanisms of action.

"The initiation of this Phase 2 trial represents a significant milestone in the advancement of PVSRIPO and our quest to treat this formidable opponent," said Matt Stober, President and Chief Executive Officer at Istari Oncology. "Currently the treatment options for patients with rGBM are limited and outcomes are grim, so following the encouraging results of our Phase 1 trial, we are eager to see the effectiveness of PVSRIPO in combination with pembrolizumab."

"Combining PVSRIPO's ability to generate antitumor immune response with a checkpoint inhibitor holds the promise of more effective therapy for this devastating disease," said W. Garrett Nichols, MD, MS, Chief Medical Officer at Istari Oncology. "Achieving rapid disease control is critical in patients with rGBM, one of the most aggressive and treatment-refractory tumors."

LUMINOS-101 is a Phase 2, single arm trial (clinicaltrials.gov NCT04479241) in patients with rGBM that aims to characterize the safety, tolerability and initial efficacy of PVSRIPO intratumoral infusion followed by intravenous pembrolizumab 14 to 28 days later, and every three weeks thereafter.

LUMINOS-101 follows a Phase 1 trial of PVSRIPO in rGBM, conducted at the Preston Robert Tisch Brain Tumor Center at Duke University Medical Center, that found survival rates were significantly higher in rGBM patients who received an intratumoral infusion of PVSRIPO compared to similar patients receiving standard treatment. Overall survival among patients who received PVSRIPO plateaued at 21 percent, 24 to 36 months after injection based on a publication of the interim trial results (Desjardins, et al., 2018 NEJM). The overall survival rate

was sustained at 36 months in these patients. A multicenter Phase 2 study of PVSRIPO in patients with rGBM (n=120) completed enrollment in June 2020; follow-up of those patients is ongoing.

The Phase 2 LUMINOS-101 trial will be conducted across multiple research sites, including Ohio State University Comprehensive Cancer Center, University of California San Francisco, Baptist MD Anderson Cancer Center, Duke University Medical Center, Oregon Health and Science University and University Hospitals Seidman Cancer Center (UHSCC) in Cleveland, Ohio. The first patient has been dosed at UHSCC, which treated seven patients with rGBM as part of the previous Phase 2 trial.

“The Phase 1 trial of PVSRIPO yielded survival rates like we’ve never seen before,” says Andrew E. Sloan, MD, FACS, Director of the Brain Tumor & Neuro-Oncology Center and the Center of Excellence in Translational Neuro-Oncology at UH Seidman Cancer Center and UH Neurological Institute, and Professor and Vice Chairman, Department of Neurosurgery at Case Western Reserve University School of Medicine. “Glioblastoma is one of the most aggressive tumors known to man. Following the encouraging results of PVSRIPO to date, we are very interested to see if those results improve further in combination with pembrolizumab.”

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 unleashes 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 Glioblastoma
Glioblastoma is the most common and aggressive form of brain cancer, comprising 52% of patients with primary brain tumors. There are approximately 13,000 patients diagnosed with GBM in the United States annually and approximately 18,000 in the European Union. Despite aggressive treatment, survival for newly diagnosed glioblastoma patients is usually less than 20 months, and for patients with recurrence, which occurs in 98% of patients, survival is usually less than 12 months.

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.

Keytruda® is a registered trademark of Merck Sharp & Dohme Corp

###

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

Investor Contact:
Stern Investor Relations
Christina Tartaglia
Email: Christina.tartaglia@sternir.com

Media Contact:
French/West/Vaughan
Emily Brice
Email: ebrice@fwv-us.com