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# **Oncolytics Biotech® Inc. Announces Phase I Study in Pediatric Patients with Relapsed or Refractory Solid Tumors to be Conducted by the Children's Oncology Group and Sponsored by the National Cancer Institute**

CALGARY, Nov. 18 /PRNewswire-FirstCall/ - Oncolytics Biotech Inc. ("Oncolytics") (TSX:ONC, NASDAQ:ONCY) announced today that the Children's Oncology Group (COG) intends to conduct a Phase I trial of REOLYSIN® in combination with cyclophosphamide in pediatric patients with relapsed or refractory solid tumors. The study will be conducted in collaboration with the Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, U.S. National Cancer Institute (NCI), which is part of the National Institutes of Health, under its Clinical Trials Agreement with Oncolytics. Oncolytics will provide clinical supplies of REOLYSIN for this study. The study chair will be Dr. E. Anders Kolb of the Nemours/Alfred I. duPont Hospital for Children.

The study is an open label, multicentre, dose escalation Phase I study of REOLYSIN in patients aged three to 21 years with relapsed or refractory solid tumors. Patients will receive intravenous REOLYSIN on days one through five of each 28-day treatment cycle. Some patients will also receive oral cyclophosphamide on days one through 21. Treatments repeat every 28 days for up to 12 cycles in the absence of disease progression or unacceptable toxicity.

The primary objectives of the trial include estimating maximum tolerated dose, and defining and describing the toxicities of REOLYSIN and REOLYSIN plus oral cyclophosphamide in this patient population. Secondary objectives include defining antitumor activity of REOLYSIN within the confines of a Phase I study, evaluating the development of neutralizing antibodies to REOLYSIN following intravenous administration of REOLYSIN alone and in combination with cyclophosphamide, and assessing the biologic activity of REOLYSIN. After completion of study treatment, patients are to be followed up periodically for up to one year.

"This trial builds on a range of completed preclinical work and clinical studies in adult patients, including a U.K. Phase I clinical study examining the use of REOLYSIN in conjunction with cyclophosphamide and a U.S. Phase II clinical study in sarcoma using REOLYSIN as a monotherapy," said Dr. Brad Thompson, President and CEO of Oncolytics. "It is very important to investigate the use of an agent in adults prior to proceeding to use in pediatric patients. With the work in adults well advanced, we can now move ahead in

younger patients."

Information on the study will be available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About the NCI**

The U.S. National Cancer Institute (NCI) is part of the National Institutes of Health and the U.S. Department of Health and Human Services. NCI's main responsibilities include coordinating the National Cancer Program; conducting and supporting cancer-related research; training physicians and scientists; and disseminating state-of-the-art information about cancer detection, diagnosis, treatment, prevention, control, palliative care, and survivorship.

### **About Oncolytics Biotech Inc.**

Oncolytics is a Calgary-based biotechnology company focused on the development of oncolytic viruses as potential cancer therapeutics. Oncolytics' clinical program includes a variety of human trials including a Phase III trial in head and neck cancers using REOLYSIN, its proprietary formulation of the human reovirus. For further information about Oncolytics, please visit: [www.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com).

*This press release contains forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including the Company's expectations related to the Phase 1 trial in pediatric patients with relapsed or refractory solid tumours sponsored by the COG in collaboration with the NCI, and the Company's belief as to the potential of REOLYSIN as a cancer therapeutic, involve known and unknown risks and uncertainties, which could cause the Company's actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue research and development projects, the efficacy of REOLYSIN as a cancer treatment, the tolerability of REOLYSIN<sup>®</sup> outside a controlled test, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize REOLYSIN, uncertainties related to the research and development of pharmaceuticals and uncertainties related to the regulatory process. Investors should consult the Company's quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Investors are cautioned against placing undue reliance on forward-looking statements. The Company does not undertake to update these forward-looking statements, except as required by applicable laws.*

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