May 19, 2015

Oncolytics Biotech® Inc. Announces Phase 1 Study in Pediatric Patients with Brain Tumors

CALGARY, May 19, 2015 /PRNewswire/ - Oncolytics Biotech Inc. ("Oncolytics") (TSX:ONC, NASDAQ:ONCY) today announced that following submission to the U.S. Food and Drug Administration ("FDA") for review, the Investigational New Drug Application containing the protocol titled "MC1472: Phase 1 Study of Replication Competent Reovirus (REOLYSIN®) in Combination with GM-CSF in Pediatric Patients with Relapsed or Refractory Brain Tumors" is now active. The study sponsor is Mayo Clinic based in Rochester, Minnesota, and the Study Chair is Dr. Richard Bram of Mayo Clinic.

"This is the first time we have been able to assess this treatment combination in patients," said Dr. Brad Thompson, President and CEO of Oncolytics. "Pediatric patients with high grade primary brain tumors have few, if any, treatment options so we are eager to determine if this regimen can make a difference for a group with poor survival outcomes."

The study is an open-label Phase I trial to clarify the safety, and determine possible efficacy, of GM-CSF given prior to administration of intravenous REOLYSIN® for children with malignant high grade brain tumors. GM-CSF will be administered on days one and two of each cycle with REOLYSIN® administered on days three, four and five. Cycles will be given every 28 days for up to 12 cycles if patients remain without evidence of tumor progression and without intolerable toxicity. The primary outcome for the nine to 18 patients of the Phase 1 study will be safety and tolerability. Secondary goals include median progression free and overall survival in this patient population.

Eligible patients include those between the ages of 10 and 21 with histologically confirmed high grade (grade 3 or 4) primary brain tumor either classified as a glioma (including astrocytoma, anaplastic oligodendroglioma and glioblastoma multiforme), medulloblastoma, atypical teratoid/rhabdoid tumor or primitive neuroectodermal tumor. Patients must have no known curative therapy available and can have had up to two chemotherapy regimens for the brain tumor previously.

Oncolytics has conducted three previous clinical studies in adults with brain cancers including gliomas, and has found that REOLYSIN® can infect a variety of brain tumors when delivered intravenously. In April 2014, the Company announced the findings from a clinical study showing that intravenously delivered REOLYSIN® can cross the blood brain barrier and a pre-clinical study in animals examining the synergies associated with treatment with GM-CSF prior to administering REOLYSIN®. The Company has received Orphan Drug Designation from the FDA for the use of REOLYSIN® in the treatment of malignant gliomas.

According to the US Central Brain Tumor Registry an estimated 4,620 new cases of primary malignant and non-malignant brain and central nervous system tumors will be diagnosed in pediatric and adolescent patients in 2015. In patients between zero and 19 years old, the overall total incidence of HGG (including anaplastic astrocytoma, anaplastic oligodendroglioma, glioblastoma, mixed glioma, and malignant glioma) is approximately 0.8 per 100,000.

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 later-stage, randomized human trials in various indications using REOLYSIN®, its proprietary formulation of the human reovirus. For further information about Oncolytics, please visit: www.oncolyticsbiotech.com.

This press release contains forward-looking statements within the meaning of the U.S. Securities Act of 1933, as amended, and U.S. Securities Exchange Act of 1934, as amended, and forward-looking information within the meaning of Canadian securities laws. Statements, other than statements of historical facts, included in this press release that address activities, events or developments that Oncolytics expects or anticipates will or may occur in the future, including such things as, the Company's expectations related to the study in pediatric patients with relapsed or refractory brain tumors, the Company's belief as to the potential of REOLYSIN® as a cancer therapeutic, and other such matters are forward-looking statements and forward-looking information and 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 and forward-looking information. Such risks and uncertainties include, among others, risks related to the statistical sufficiency of patient enrollment numbers in separate patient groups, the availability of funds and resources to pursue research and development projects, the efficacy of REOLYSIN® as a cancer treatment, the tolerability of REOLYSIN® 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 and forward-looking information. Investors are cautioned against placing undue reliance on forward-looking statements and forward-looking information. The Company does not undertake to update these forward-looking statements and forward-looking information, except as required by applicable laws.

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