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Oncolytics Biotech Inc. Announces Approval for U.K. Clinical Trial Investigating REOLYSIN(R) in Combination with Gemcitabine

CALGARY, Jan. 3 /PRNewswire-FirstCall/ - Oncolytics Biotech Inc. ("Oncolytics") (TSX:ONC, NASDAQ:ONCY) announced today that it has received a letter of approval from the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) for its Clinical Trial Application (CTA) to begin a clinical trial using intravenous administration of REOLYSIN(R) in combination with gemcitabine (Gemzar(R)) in patients with advanced cancers including pancreatic, lung and ovarian. The principal investigators are Dr. Johann de Bono of The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, London and Professor Jeff Evans of the University of Glasgow and the Beatson Oncology Centre in Glasgow, Scotland. Gemcitabine is used in patients with lung, pancreatic and ovarian cancers and is also used widely in the treatment of many other types of cancers.

"The combination of REOLYSIN(R) and gemcitabine was synergistic in preclinical studies," said Dr. Brad Thompson, President and CEO of Oncolytics. "The data gathered in this study is expected to assist the company in further defining the optimal path to product registration. Drug combination studies allow us to investigate REOLYSIN(R) with drugs that are part of the current standard of care."

Preclinical studies conducted at Cornell University demonstrated that the combination of gemcitabine and REOLYSIN(R) was synergistic against selected cancer cell lines. This work was verified by additional studies conducted by the U.S. National Cancer Institute (NCI).

This trial (REO 009) has two components. The first is an open-label, dose-escalating, non-randomized study of REOLYSIN(R) given intravenously with gemcitabine every three weeks. A standard dosage of gemcitabine will be delivered with escalating dosages of REOLYSIN(R) intravenously. A maximum of three cohorts will be enrolled in the REOLYSIN(R) dose escalation portion. The second component of the trial will immediately follow and will include the enrolment of a further 12 patients at the maximum dosage of REOLYSIN(R) in combination with a standard dosage of gemcitabine.

Eligible patients include those who have been diagnosed with advanced or metastatic solid tumours including pancreatic, lung and ovarian cancers that are refractory (have not responded) to standard therapy or for which no curative standard therapy exists. The primary objective of the trial is to determine the Maximum Tolerated Dose (MTD), Dose-Limiting Toxicity (DLT), recommended dose and dosing schedule and safety profile of REOLYSIN(R) when administered in combination with gemcitabine. Secondary objectives include the evaluation of immune response to the drug combination, the body's response to the drug combination compared to chemotherapy alone and any evidence of anti-tumour activity.

In the U.K. and the U.S., approximately 280,000 people are diagnosed with pancreatic, lung and ovarian cancers every year.

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 Phase I and Phase II human trials using REOLYSIN(R), its proprietary formulation of the human reovirus, alone and in combination with radiation or chemotherapy. For further information about Oncolytics, please visit www.oncolyticsbiotech.com

For more information about Gemzar(R), go to www.gemzar.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 U.K. combination REOLYSIN(R)/gemcitabine clinical trial, and the Company's belief as to the potential of REOLYSIN(R) 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(R) as a cancer treatment, the tolerability of REOLYSIN(R) outside a controlled test, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize REOLYSIN(R), 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.

SOURCE Oncolytics Biotech Inc.