Oncolytics Biotech® Inc. Announces Publication of Phase I Clinical Trial Results Examining Combination of REOLYSIN® and Docetaxel in Clinical Cancer Research

CALGARY, Nov. 29 /PRNewswire-FirstCall/ - Oncolytics Biotech Inc. (“Oncolytics”) (TSX:ONC, NASDAQ:ONCY) announced today that a paper entitled "REO-10: A Phase I Study of Intravenous Reovirus and Docetaxel in Patients with Advanced Cancer," was recently published by Comins et al. in the journal Clinical Cancer Research (Clin Cancer Res 16(22):5564-5572).

The paper reports final results from a combination REOLYSIN and docetaxel trial, (REO 010) designed to evaluate the anti-tumour effects of systemic administration of REOLYSIN in combination with docetaxel (Taxotere®) in patients with advanced cancers. Patients received docetaxel on day one (75mg/m²) and escalating doses of reovirus up to $3 \times 10^{10}$ TCID$_{50}$ on days one through five, every three weeks. The principal investigator was Professor Hardev Pandha of the Royal Surrey County Hospital, U.K.

Twenty-five patients were enrolled, with 24 being exposed to treatment and 23 completing at least one cycle of therapy. Sixteen patients were suitable for response assessment. The combination was deemed to be safe and well tolerated and a maximum tolerated dose was not reached. Antitumour activity was seen with one complete response (in the liver of a breast cancer patient with no evidence of disease recurrence at the end of the study, following eight cycles of treatment) and three partial responses. A disease control rate (combined complete response, partial response and stable disease) of 88% was observed. The authors concluded that the combination of reovirus and docetaxel is safe, with evidence of objective disease response, and warrants further evaluation in a Phase II study at a recommended schedule of docetaxel (75mg/m², three times weekly) and reovirus ($3 \times 10^{10}$ TCID$_{50}$, days one to five, every three weeks).

Eligible patients included those who had been diagnosed with advanced or metastatic solid tumours including bladder, lung, prostate or upper gastro-intestinal cancers that were refractory (had not responded) to standard therapy or for which no curative standard therapy existed. The primary objective of the trial was to determine the MTD, Dose-Limiting Toxicity, recommended dose and dosing schedule and safety profile of REOLYSIN when administered in combination with docetaxel. Secondary objectives included 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.

"These findings demonstrate a clear benefit for patients, even at lower doses, and provide us with additional patient data on another REOLYSIN/chemotherapy combination that we may elect to advance into later stage testing in the future," said Dr. Brad Thompson, President and CEO of Oncolytics.

**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 implication of the materials presented in "Clinical Cancer Research" with respect to REOLYSIN, 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 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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