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Oncolytics Biotech(R) Inc. Announces Opening of Enrollment in Phase 3 Trial for REOLYSIN(R) in Head and Neck Cancers

CALGARY, May 25 /PRNewswire-FirstCall/ - Oncolytics Biotech Inc. ("Oncolytics") (TSX:ONC, NASDAQ:ONCY) today announced that it has opened enrollment in its Phase 3 trial examining REOLYSIN in combination with paclitaxel and carboplatin in patients with platinum-refractory head and neck cancers. The Company had previously received approval from the U.S. Food and Drug Administration (FDA) under the Special Protocol Assessment (SPA) process and the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) to conduct the trial in those countries, respectively. Oncolytics intends to conduct the first stage of the trial at approximately 25 centres in the U.S., U.K., and Belgium but may elect to add centres in additional countries.

"Opening enrollment in our first pivotal study in an important step forward in our increasingly late stage REOLYSIN clinical program," said Dr. Brad Thompson, President and CEO of Oncolytics. "We expect enrollment to ramp up over the next quarter as additional centres come on line as the trial progresses."

As previously disclosed, the randomized, two-arm, double-blind, multicentre, two-stage, adaptive Phase 3 trial will assess the intravenous administration of REOLYSIN with the chemotherapy combination of paclitaxel and carboplatin versus the chemotherapy alone in patients with metastatic or recurrent squamous cell carcinoma of the head and neck, or squamous cell cancer of the nasopharynx, who have progressed on or after prior platinum-based chemotherapy. All patients will receive treatment every three weeks (21 day cycles) with paclitaxel and carboplatin and will also receive, on a blinded basis, either intravenous placebo or intravenous REOLYSIN. All dosing takes place in the first five days of each cycle with all patients receiving standard intravenous doses of paclitaxel and carboplatin on day one only, and on days one through five, either intravenous placebo or intravenous REOLYSIN at a dose of 3x1010 TCID50. Patients may continue to receive the trial combination therapy for up to eight, 21-day cycles and, thereafter, blinded placebo or blinded REOLYSIN until the patient has progressive disease or meets other criteria for removal from the trial.

The primary endpoint for the trial is overall survival (OS); secondary endpoints include progression free survival (PFS), objective response rate (complete response (CR) + partial response (PR)) and duration of response, and safety and tolerability of REOLYSIN when administered in combination with paclitaxel and carboplatin. The first stage of the trial is designed to enroll 80 patients. The second stage is adaptive, and is designed to enroll between 100 and 400 patients with the most probable statistical enrolment being 195 patients in this stage. This adaptive trial design allows frequent data evaluation to determine if the probability of reaching a statistically significant endpoint has been achieved.

The decision to pursue a Phase 3 trial in head and neck cancers was predicated on positive results seen in the Company's U.K. Phase 1 and Phase 2 combination REOLYSIN and paclitaxel/carboplatin clinical trials, as well as significant preclinical work demonstrating synergy in combination with taxane or platinum-based drugs. Updated results from the U.K. Phase 1/2 trial reported in November 2009 demonstrated an overall response rate (PR and CR) of 42% and a total clinical benefit rate (PR + CR + stable disease) of 74%. The Company is currently conducting a confirmatory Phase 2 trial in the U.S. in patients with advanced head and neck cancers.

About REOLYSIN

REOLYSIN is a proprietary formulation of the human reovirus that acts primarily as a direct cytotoxic agent. Reovirus is naturally occurring (not genetically engineered) and has been demonstrated to replicate specifically in tumour cells bearing an activated Ras pathway, leaving healthy normal cells intact. At least two thirds of carcinomas and more than 90% of metastatic disease has Ras involvement.

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.

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 3 combination REOLYSIN and paclitaxel/carboplatin trial for patients with platinum-refractory head and neck cancers, the planned timing and implementation of the Phase 3 trial, 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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