Oncolytics Biotech® Announces ASCO Abstracts and Preliminary Data for Studies in Pancreatic and Prostate Cancers

CALGARY, May 17, 2017 /PRNewswire/ - Oncolytics Biotech® Inc. (Oncolytics or the Company) (TSX:ONC) (OTCQX:ONCYF) today announced the publication of abstracts for an open-label phase 1b trial in patients with metastatic adenocarcinoma of the pancreas (MAP) (REO 024) and an open-label, randomized, phase 2 study in metastatic castration resistant prostate cancer (mCRPC). Data from the studies will be presented during the American Society of Clinical Oncology (ASCO) Annual Meeting, June 2-6, in Chicago, IL.

REO 024, a phase 1b study, was designed to assess the safety (primary endpoint) and dose-limiting toxicity of REOLYSIN® in combination with pembrolizumab (KEYTRUDA®) and chemotherapy in patients with histologically confirmed MAP who have failed, or did not tolerate, first-line treatment. The study enrolled 11 patients who were given REOLYSIN plus pembrolizumab, along with one of gemcitabine, 5-fluouracil or irinotecan. Grade 1 and 2 treatment emergent adverse events (TEAE) occurred in all patients and Grade 3 and 4 TEAE occurred in eight patients. Three of five efficacy evaluable patients showed a tumor response (secondary endpoint), with one having a partial response (six-month duration) and two having stable disease (lasting 126 and 221 days). Investigators noted that on-treatment biopsies revealed reovirus infection in cancer cells and immune infiltrates and concluded that the combination therapy showed manageable safety profiles and anti-tumour activity in previously treated MAP patients. The abstract, authored by Mahalingam et al, "A study of REOLYSIN in combination with Pembrolizumab and chemotherapy in patients (pts) with relapsed metastatic adenocarcinoma of the pancreas (MAP)," is now available on the ASCO annual meeting website.

"We continue to expand our library of clinical data and establish REOLYSIN as safe in combination with KEYTRUDA, a highly promising checkpoint inhibitor," said Dr. Andres Gutierrez, CMO of Oncolytics. "This is a major first step in supporting the adaptive immunity component of our clinical development plan, and it opens the door for additional collaborations with other checkpoint inhibitors as we advance the longer-term, immuno-oncology portion, of the clinical development plan. We look forward to announcing further developments for this program later in the year."

The phase 2 study in prostate cancer was an 85-patient trial designed and executed by the Canadian Cancer Trials Group (CCTG) (IND 209) to assess the therapeutic combination of intravenously-administered REOLYSIN given in combination with docetaxel/prednisone versus docetaxel/prednisone alone in patients with mCRPC. The study did not meet its primary endpoint of 12-week lack of progression, which was comparable in both the test and control arms, or the secondary endpoint of overall survival. The abstract reports significant differences at baseline, where more patients had poor prognostic factors for survival in the
test arm versus the control arm. In addition, while the combination of REOLYSIN and docetaxel was tolerated, dose reductions were more common on the test arm with only 51 percent of the patients receiving 90% of the planned dose intensity of docetaxel, versus 76 percent on the control arm.

"In recent years, we and our collaborators have performed numerous phase 1b and phase 2 trials to better understand the anti-tumour mechanisms of REOLYSIN, to identify the best therapies to pair with REOLYSIN, and to identify the cancer indications for which REOLYSIN provides clear benefit," said Dr. Matt Coffey, President and CEO of Oncolytics. "Collectively, these findings reinforce our Clinical Development Plan. While these results themselves indicate that prostate cancer is likely not a viable tumor target, they do not impact our focus on the advancement of REOLYSIN into a phase 3 registration study in patients with metastatic breast cancer. We thank the investigators, staff and patients that participated in these trials that delivered very important data to guide the late stage development of REOLYSIN toward patient populations that can most benefit from its immune-oncology effects."

The abstract, authored by Eigl et al, "A randomized phase II study of pelareorep (REO) plus docetaxel vs. docetaxel alone in patients with metastatic castration resistant prostate cancer (mCRPC): Canadian Cancer Trials Group study IND 209," is now available on the ASCO annual meeting website.

About Oncolytics Biotech Inc.
Oncolytics is a biotechnology company developing REOLYSIN, an immuno-oncology viral-agent, as a potential treatment for a variety of tumor types. The compound induces selective tumor lysis and promotes an inflamed tumor phenotype through innate and adaptive immune responses to treat a variety of cancers. Oncolytics’ clinical development program emphasizes three pillars: chemotherapy combinations to trigger selective tumor lysis; immuno-therapy combinations to produce adaptive immune responses; and immune modulator (IMiD) combinations to facilitate innate immune responses. Oncolytics is currently planning its first registration study in breast cancer, as well as studies in combination with checkpoint inhibitors and IMID/targeted therapies in solid and hematological malignancies. 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 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including the Company’s expectations related to the Phase 2 clinical trial in prostate cancer and the Phase 1b trial in pancreatic cancers, future trials in these indications, 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, development and manufacturing of pharmaceuticals, changes in technology, general changes to the economic environment 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 should consider statements that include the words "believes", "expects", "anticipates", "intends", "estimates", "plans", "projects", "should", or other expressions that are predictions of or indicate future events or trends, to be uncertain and forward-looking. 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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