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## Oncolytics Biotech® Inc. Announces Phase 2 Study in Female Patients with Colorectal Cancer Metastatic to the Liver

CALGARY, June 29, 2016 /PRNewswire/ - Oncolytics Biotech Inc. ("**Oncolytics**" or the "**Company**") (TSX: ONC) (OTCQX: ONCYF) (FRA: ONY) 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 "Phase 2 study of REOLYSIN® (pelareorep) in combination with FOLFOX6, bevacizumab and pembrolizumab in female patients with KRAS-mutant colorectal cancer metastatic to the liver" is now active.

"This study is intended to confirm the encouraging objective overall and liver metastases response rates in female patients that we saw in a sponsored randomized Phase II study conducted in Canada," said Dr. Brad Thompson, President and CEO of Oncolytics. "We are adding a checkpoint inhibitor to the treatment regimen based on our evolving understanding of how REOLYSIN® upregulates immune responses and how the combination may make cancer cells more susceptible to attack by the immune system."

This is a multicenter, single arm safety and efficacy study of REOLYSIN® in combination with chemotherapy (FOLFOX6), bevacizumab (Avastin®) and pembrolizumab (KEYTRUDA®) in female patients with KRAS-mutant metastatic colorectal cancer (CRC) in the liver. The primary objective is to evaluate the overall response rate (ORR) according to Immune-related Response Evaluation Criteria in Solid Tumors ("**irRECIST**"). Secondary objectives include evaluating disease response in liver metastases and overall survival. The Company also intends to examine the effect of study treatment on immune-related cells and biomarkers associated with immune response; and genetic biomarkers associated with positive response to study treatment. Study enrollment will be approximately 30 patients.

Oncolytics recently announced data from a sponsored Phase 2 study of REOLYSIN®, in combination with FOLFOX6 and bevacizumab in patients with advanced or metastatic CRC (IND 210). In that study, the overall test arm had an objective response rate of 52.9% (n=51) versus 34.6% (n=52) in the control arm (p=0.06). The Company conducted a pre-planned analysis of patient responses by gender, as specified in the study protocol. The female patients in the test arm had an objective response rate of 63.2% (n=19) versus 23.8% (n=21) in the control arm (p=0.0054), and in the test arm had a median overall survival of 19.3 months (n=19) versus 14.5 months (n=21) in the control arm. The overall survival was an interim analysis, as 62 of 103 patients overall were alive at the time of data cut off. The male patients in the test arm had an objective response rate of 46.9% (n=32) versus 41.9% (n=31) in the control arm (p=0.6747). For patients (both male and female) who had metastases to the liver, those treated with REOLYSIN® had objective tumour response rates of 55% (n=40), versus 28.6% (n=42) for those who did not receive REOLYSIN® (p=0.0077).

## **About Colorectal Cancer**

The American Cancer Society estimates that 134,490 Americans (63,670 women) will be diagnosed with colorectal cancer and an estimated 49,190 Americans (23,170 women) will die from the disease in 2016. The five- and ten-year survival rates are 65% and 58%, respectively, however five-year survival drops to 13% in cases where the cancer spreads to other parts of the body, away from the primary tumour.

## **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<sup>®</sup>, 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 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 phase 2 study in female patients with colorectal cancer metastatic to the liver, the Company's belief as to the potential of REOLYSIN<sup>®</sup> 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<sup>®</sup> as a cancer treatment, the tolerability of REOLYSIN<sup>®</sup> outside a controlled test, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize REOLYSIN<sup>®</sup>, 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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