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Oncolytics Biotech® Inc. Announces Registration Pathway and Clinical Development Plan

--Initial Registration Pathway to Focus on Chemotherapy Combinations in Patients with Metastatic Breast Cancer--

CALGARY, April 12, 2017 /PRNewswire/ - Oncolytics Biotech® Inc. (TSX:ONC) (OTCQX:ONCYF) today announced its initial registration pathway and clinical development plan for REOLYSIN®, its proprietary immuno-oncology viral agent. The Company's clinical development plan has two main objectives. The primary objective is to obtain regulatory approval for REOLYSIN as quickly as possible and is based on the compelling metastatic breast cancer survival data recently presented at the American Academy of Cancer Research (AACR) Annual Meeting, in Washington, D.C. The second objective is to expand REOLYSIN into commercially valuable new treatment areas that include immunotherapy and immunomodulatory (IMiD) agents in collaboration with pharmaceutical partners.

Registration Path in Metastatic Breast Cancer
At AACR the Canadian Cancer Trials Group (CCTG) presented positive overall survival (OS) data from an open-label, randomized, phase 2 study assessing the therapeutic combination of intravenously-administered REOLYSIN given in combination with the chemotherapy agent paclitaxel versus paclitaxel alone, in patients with advanced or metastatic breast cancer (IND 213). Based on CCTG's compelling clinical results in this indication, where the combined treatment demonstrated a statistically significantly increase in median OS, the Company has consulted with key opinion leaders to develop a registration strategy. Management believes that these results are the most compelling data generated by the Company to date and will support a rapid route to market in an important therapeutic area.

The 74-patient study, powered to 90% and designed by the CCTG, reported that in the intention-to-treat patient population there was a statistically significant improvement in median OS from 10.4 months on the control arm to 17.4 months on the test arm (Hazard Ratio 0.65, 80% CI 0.46-0.91, p=0.1). The presentation also indicated that of the 74 patients in the study, 82 percent (61 patients) presented with mutated p53 tumors. The results showed that patients with mutant p53 metastatic breast cancer who were treated with REOLYSIN in combination with paclitaxel (n=30) had a median OS of 20.9 months versus 10.4 months in patients treated only with paclitaxel (n=31) (Hazard Ratio 0.52, 80% CI 0.35-0.76, p = 0.03).

The Company intends to present this data to regulators as part of an End-of-Phase 2 Meeting with a focus on obtaining scientific advice to support a registration pathway. Specific features of any future clinical studies are expected to include: overall survival as a primary

endpoint; other exploratory endpoints to identify potential markers of response; and a trial design to ensure a sufficient number of patients are run to reach a statistically significant outcome while balancing the financial resources required.

"We have developed a comprehensive clinical plan for REOLYSIN predicated on its mechanism of action, excellent safety profile with more than one thousand patients treated and the compelling overall survival data recently announced in metastatic breast cancer," said Dr. Matt Coffey, President and CEO of Oncolytics. "The registration path in the near term will look at combinations of REOLYSIN and chemotherapy agents, beginning with metastatic breast cancer. In parallel, we intend to look at other pillars of the platform and our long-range focus for REOLYSIN includes establishing collaborations with large pharma to study both immunotherapy and immunomodulatory drug combinations, such as the recently announced collaboration with Myeloma UK and Celgene using Revlimid® and Imnovid® in combination with REOLYSIN in myeloma patients."

Mechanism of Action
REOLYSIN is a first-in-class, systemically administered, immuno-oncology viral agent with a robust safety history. During the last few years, in both single-arm and randomized phase 2 clinical studies, REOLYSIN, in combination with various chemotherapeutic agents, has shown a trend to improve OS in certain indications and patient populations, while having a limited impact on objective response rate (ORR) or progression-free survival (PFS). This therapeutic profile is consistent with those observed with approved immunotherapies, where patients receive OS benefit, the gold standard of registrational endpoints, without seeing meaningful improvements in ORR or PFS.

REOLYSIN has multiple components to its mechanism of action (MOA):

- **Direct tumor lysis –** selective viral replication in permissive cancer cells leading to tumor cell lysis;
- **Innate immune response –** viral replication resulting in a cascade of chemokines/cytokines causing NK (natural killer) cells to recognize and attack cancer cells; and
- **Adaptive immune response –** antigen presenting cells (APCs) display tumor-associated antigens (TAA) and viral-associated antigens (VAA) to educate T-cells to recognize and destroy cancer cells.

Clinical Development Plan
Based on Oncolytics' evolving understanding of REOLYSIN's mechanism of action, along with survival data generated to date, the Company is dedicated to the metastatic breast cancer program as its primary focus to quickly move the agent towards a commercial path. In parallel, management has identified two additional pathways that will be advanced simultaneously in collaboration with large pharma colleagues to support the second objective of expanding REOLYSIN into commercially valuable new treatment areas:

Combinations with IMiDs
The initial activity supporting the innate immunity component of REOLYSIN's MOA, is in collaboration with cancer charity Myeloma UK and Celgene. MUK *eleven* was launched in March of this year: a first of its kind immunotherapy trial that aims to modulate the immune system to target myeloma. The Phase 1b trial will study REOLYSIN in combination with

Celgene's Imnovid® (pomalidomide) or Revlimid® (lenalidomide) as a rescue treatment in relapsing myeloma patients. The dose escalation trial will look at the safety and tolerability of these combinations, and will investigate whether the addition of REOLYSIN extends disease control in this patient group.

The trial will recruit approximately 44 patients across up to six Myeloma UK Clinical Trial Network centres in the UK. MUK *eleven* is part of the Myeloma UK Clinical Trial Network, a portfolio of early-stage trials coordinated by the Clinical Trials Research Unit at the University of Leeds, which aims to test and speed up access to promising new treatments for patients.

Oncolytics and Celgene UK & Ireland are providing their respective products for MUK *eleven*: Oncolytics is providing REOLYSIN and Celgene UK & Ireland is providing Imnovid® and Revlimid®.

Combinations with Immunotherapy
In support of the adaptive immunity component of the MOA, the Company is currently running its first study in combination with an emerging class of immuno-oncology agents known as checkpoint inhibitors. REO 024 is an open-label phase 1b trial to determine the safety and dose-limiting toxicity of REOLYSIN in combination with pembrolizumab (KEYTRUDA®) and chemotherapy in patients with histologically confirmed, advanced or metastatic pancreatic adenocarcinoma who have failed, or did not tolerate, first-line treatment. The goal of this study is to establish the safety profile of the REOLYSIN/KEYTRUDA combination and to determine how a checkpoint inhibitor could improve the immune system's ability to recognize cancer cells through the stimulation of the adaptive immune response in patients caused by REOLYSIN. The Company expects to report on the safety data from REO 024 in 2017 and looks to expand its clinical collaborations using other checkpoint inhibitor agents and investigating different indications, dose levels and efficacy.

"While our near-term focus will be on chemotherapy combinations, our longer-term goal is to establish REOLYSIN as the backbone of an immuno-oncology regimen in combination with other agents, including checkpoint inhibitors and other immunomodulatory drugs," said Dr. Andres Gutierrez, Chief Medical Officer of Oncolytics. "The combinations with emerging immunotherapies could be transformative when taking into account REOLYSIN's continuing positive safety profile in ongoing studies."

In summary, in 2017 Oncolytics expects to make progress against a number of milestones including:

- Discussions with regulators focused on obtaining scientific advice on the best registration path in metastatic breast cancer;
- Announcing a detailed registration study in metastatic breast cancer;
- Reporting safety data from the phase 1b REO 024 pancreatic cancer study evaluating REOLYSIN in combination with pembrolizumab (KEYTRUDA®); and
- Expanding clinical collaborations with large pharma in an effort to support further development around the innate and adaptive immunity components of REOLYSIN's MOA.

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.

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 breast cancer, future trials in this indication, the potential for additional data from other studies, the potential for collaborations, 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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