

Oncolytics Biotech® Inc. Announces FDA Fast Track Designation for REOLYSIN® in Metastatic Breast Cancer

CALGARY, May 8, 2017 /PRNewswire/ - Oncolytics Biotech® Inc. (Oncolytics or the Company) (TSX:ONC) (OTCQX:ONCYF) announced today that the United States Food and Drug Administration (FDA) has granted Fast Track designation for REOLYSIN®, the Company's proprietary immuno-oncology viral agent, for the treatment of metastatic breast cancer.

"Fast Track designation represents an important step for our clinical development plan, which is squarely focused on a registration pathway in metastatic breast cancer and advancing REOLYSIN to regulatory review as quickly as possible," said Dr. Matt Coffey, President and CEO of Oncolytics Biotech. "Our goal is to conduct an End-of-Phase 2 meeting with the FDA as soon as is practical and obtain scientific guidance. We are eager to leverage this designation and use the opportunity for more frequent dialogue with the FDA, as well as the potential for an expedited review process, to support the future development of REOLYSIN."

In April 2017, 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) was presented at the American Association of Cancer Research Annual Meeting. The combined treatment demonstrated a statistically significant increase in median overall survival. Based on Oncolytics' evolving understanding of REOLYSIN's mechanism of action, along with the positive overall survival data generated to date, the Company is pursuing metastatic breast cancer as its primary focus for late-stage clinical testing.

The FDA's Fast Track process is designed to facilitate the development, and expedite the review of drugs that treat serious conditions and fill an unmet medical need. Fast Track designation supports more frequent dialogue with the FDA on a company's drug development plan, data requirements and clinical trial design. It also, in certain situations, enables the FDA to take action on a new drug or biologics license application more rapidly than under the standard review process.

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 and the presentation related thereto contain 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 belief as to the potential of REOLYSIN® as a cancer therapeutic; the Company's expectations as to the success of its research and development programs in 2017 and beyond, the Company's planned operations, the value of the additional patents and intellectual property; the Company's expectations related to the applications of the patented technology; the Company's expectations as to adequacy of its existing capital resources; the design, timing, success of planned clinical trial programs; and other statements related to anticipated developments in the Company's business and technologies 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 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, uncertainties related to the regulatory process and general changes to the economic environment. 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 forwardlooking statements, except as required by applicable laws.

SOURCE Oncolytics Biotech Inc.