

September 11, 2017



# Oncolytics Biotech® Announces the Presentation of REOLYSIN® Clinical Data at ESMO 2017 Congress

***Additional randomized phase 2 data in metastatic breast cancer demonstrates doubling of overall survival in Hormone Receptor Positive (ER+PR+)/HER2- patients***

***Largest immuno-oncolytic virus safety database reported to-date demonstrates REOLYSIN® is safe and well-tolerated***

CALGARY and SAN DIEGO, Sept. 11, 2017 /PRNewswire/ - Oncolytics Biotech® Inc. (TSX: ONC) (OTCQX: ONCYF) (Oncolytics or the Company), a biotech company developing REOLYSIN®, a first-in-class, systemically delivered immuno-oncolytic virus that activates the innate and adaptive immune systems, today announced that two poster presentations focused on REOLYSIN were presented on Sunday, September 10 at the European Society for Medical Oncology (ESMO) 2017 Congress.

- 1193P, *Pooled data analysis of the safety and tolerability of intravenous Pelareorep in combination with chemotherapy in 500 + cancer patients*, Dr. Andres Gutierrez, Oncolytics Biotech

"Our poster on pooled data outlines the largest safety database available to date for an oncolytic virus and demonstrates that REOLYSIN is safe and well tolerated when administered in combination with chemotherapy," said Dr. Matt Coffey, President and CEO of Oncolytics Biotech. "Regarding the metastatic breast cancer data presented within this pooled safety data, further analysis of our phase two study highlights a doubling of overall survival benefit for patients with hormone receptor double-positive, HER2-negative breast cancer – a major genetic subgroup – when treated with REOLYSIN/paclitaxel combination treatment versus paclitaxel alone. The poster demonstrates a strong safety profile and statistically significant efficacy as we continue to advance towards regulatory approval for REOLYSIN in this indication."

In the IND 213 randomized phase 2 study in metastatic breast cancer, conducted by the Canadian Cancer Trials Group, HR+ (ER+/PR+) / HER2- patients (n=47) demonstrated that the test arm of REOLYSIN/paclitaxel more than doubled median overall survival (OS) from 10.8 months on the control arm (paclitaxel alone) to 21.8 months. The hazard ratio was 0.36 and p-value was 0.003. The ITT (intent-to-treat) group (n=74, all genetic subtypes) improved median OS from 10.4 months on the control arm to 17.4 months on the test arm. The topline ITT data was initially announced at the American Association for Cancer Research in April 2017, continues to mature and we are hopeful that complete OS data is made available in the future.

Highlights of the pooled safety data study include:

- **Adverse events reported most frequently by REOLYSIN-treated patients were reversible Grade 1 and 2 events, including fever, chills, fatigue and the gastrointestinal-related AEs of nausea, vomiting, diarrhea.**
- **REOLYSIN did not modify or increase chemotherapy-induced Grade 3 or 4 treatment-emergent adverse events (TEAEs).**
- **Certain serious TEAEs were more common in the REOLYSIN-treated arms, however the incidence of serious AEs due to febrile neutropenia and/or infection was similar in each group.**

Oncolytics recently attended an End-of-Phase 2 meeting with the United States Food and Drug Administration (FDA), which addressed registration pathways for REOLYSIN for the treatment of metastatic breast cancer, the indication for which the FDA has granted Fast Track designation. The Company will announce the outcome of this meeting after receiving the formal minutes from the agency and expects to announce the outcome of any filings coming as a result of this meeting before the end of the year.

- *523P, Mechanism of Pelareorep (Pel)-mediated cell death in a Phase I study in combination with irinotecan/ fluorouracil/ leucovorin/ bevacizumab (FOLFIRI/B) in patients with KRAS mutant metastatic colorectal cancer (mCRC), Dr. Sanjay Goel, Montefiore Medical Center, NY*

Poster 523, presented by Dr. Sanjay Goel of Montefiore Medical Center in New York, characterizes the mechanism of pelareorep-mediated cell death. The phase 1 trial studied the combination of REOLYSIN with irinotecan/ fluorouracil/ leucovorin/ bevacizumab (FOLFIRI/B) in patients with KRAS mutant metastatic colorectal cancer. The study found that REOLYSIN is safe and well tolerated in combination with FOLFIRI/B, and suggests that REOLYSIN compromises cancer cell integrity via a novel mechanism of viral-mediated cytotoxicity.

### **About REOLYSIN**

REOLYSIN® is a non-pathogenic, proprietary isolate of the unmodified reovirus: a first-in-class systemically delivered immuno-oncolytic virus for the treatment of solid tumors and hematological malignancies. The compound induces selective tumor lysis and promotes an inflamed tumor phenotype through innate and adaptive immune responses to treat a variety of cancers.

### **About Oncolytics Biotech Inc.**

Oncolytics is a biotechnology company developing REOLYSIN, a systemically delivered immuno-oncolytic virus. 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 metastatic breast cancer, as well as studies in combination with checkpoint inhibitors as well as targeted and IMiD 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 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements, including the Company's belief as to the potential of REOLYSIN<sup>®</sup> 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 forward-looking statements, except as required by applicable laws.*

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