

December 5, 2017



# **Oncolytics Biotech® Receives Favorable Final Advice Letter from the European Medicines Agency for REOLYSIN® in Metastatic Breast Cancer**

- Proposed phase 3 study design is found acceptable and can form the basis of a Marketing Authorization Application (MAA)
- Feedback continues to support our focus on HR+/HER2- patients that reported a statistically significant increase in median overall survival by nearly doubling from 10.8 to 21.0 months
- EMA advice consistent with feedback received from FDA paving the way for a global phase 3 study

CALGARY and SAN DIEGO, CA, Dec. 5, 2017 /PRNewswire/ - Oncolytics Biotech® Inc. (TSX: ONC) (OTCQX: ONCYF) (Oncolytics or the Company), a biotech company developing REOLYSIN®, also known as pelareorep, an intravenously delivered immuno-oncolytic virus that activates the innate and adaptive immune systems to turn 'cold' tumors 'hot', today announced that the company has received a favorable Final Advice Letter from the European Medicines Agency (EMA). The Letter refers to the proposed use of pelareorep in combination with paclitaxel, for the treatment of hormone receptor positive, HER2 receptor negative (HR+/HER2-) metastatic breast cancer patients in a pivotal phase 3 registration study and suggests that a single 400-patient study may be acceptable to form the basis of a Marketing Authorization Application (MAA) in Europe.

"The EMA's feedback and Final Advice Letter are very much inline with the feedback and advice we received from the FDA in September and adds to the support we have for our proposed target patient population of HR positive/HER2 negative metastatic breast cancer patients for the registration study," said Dr. Matt Coffey, President and CEO of Oncolytics Biotech. "Our statistically significant and clinically compelling overall survival data, Fast Track designation and clear guidance from the FDA and EMA allow us to focus on the completion of the adaptive study design that will include approximately four hundred patients with a pre-determined interim analysis at two hundred patients. Furthermore, the EMA provided guidance that if the study achieves its primary endpoint, it may form the basis of a Marketing Authorization Application for commercialization in Europe. The design of the study, feedback from both the FDA and EMA and our recently announced partnership with Adlai Nortye will also drive our ongoing partnering process."

Oncolytics' proposed target population for its phase 3 study of pelareorep is patients with HR+/HER2- mBC, which represents approximately 73 percent of metastatic breast cancer cases that have limited treatment options that offer survival benefit. Details of the pivotal phase 3 registration study will be made available following evaluation and completion of

discussions with clinical advisors and potentially partners.

### **About Metastatic Breast Cancer**

Metastatic breast cancer, also known as advanced or Stage 4 breast cancer, has spread to other parts of the body. Most commonly the lungs, liver, bones or brain. The disease affects over 154,000 women in the United States and according to the American Cancer Society, has a five-year survival rate of just 22 percent. Significantly lower than stage 3, with a five-year relative survival rate of 72 percent and stage 2, with a five-year survival rate over 90 percent.

### **About REOLYSIN/Pelareorep**

REOLYSIN, also known as pelareorep, is a non-pathogenic, proprietary isolate of the unmodified reovirus: a first-in-class intravenously 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, also known as pelareorep, an intravenously delivered immuno-oncolytic virus. The compound induces selective tumor lysis and promotes an inflamed tumor phenotype – turning 'cold' tumors 'hot' – 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 and 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 and forward-looking information under applicable Canadian securities laws (such forward-looking statements and forward-looking information are collectively referred to herein as "forward-looking statements"). Forward-looking statements, including the Company's belief as to the potential of REOLYSIN<sup>®</sup> as a cancer therapeutic; the Corporation's proposed use of REOLYSIN in combination with paclitaxel, for the treatment of hormone receptor positive, HER2 receptor negative (HR+/HER2-) metastatic breast cancer (mBC) patients in a phase 3 registration study; the potential basis for a marketing authorization application (MAA) in Europe; the Corporation's proposed target patient population of HR positive/HER2 negative metastatic breast cancer patients for the registration study; the proposed characteristics for an adaptive study design; the Corporation's plans for future partnering arrangements; the timing of release of details of the Corporation's proposed phase 3 registration study; the Company's plans regarding its first registration study in metastatic breast cancer and studies in combination with checkpoint inhibitors and IMiD therapies in solid and hematological malignancies; 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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