Oncolytics Biotech® Receives Special Protocol Assessment Agreement from FDA for Phase 3 Clinical Trial of Pelareorep In Metastatic Breast Cancer

CALGARY, Alberta and SAN DIEGO, May 10, 2018 (GLOBE NEWSWIRE) -- Oncolytics Biotech® Inc. (TSX:ONC) (OTCQX:ONCYF), currently developing REOLYSIN® (pelareorep), an intravenously delivered immuno-oncolytic virus turning cold tumors hot, today announced that it has reached an agreement with the U.S. Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for the protocol design, clinical endpoints and statistical analysis approach for the company's phase 3 study evaluating pelareorep for the treatment of metastatic breast cancer. The company previously received Fast Track Designation for pelareorep for the treatment of metastatic breast cancer in May 2017.

"This agreement with the FDA, outlining the specific clinical pathway forward in metastatic breast cancer, is an important milestone in advancing pelareorep along a path to potential regulatory approval," said Dr. Matt Coffey, President and CEO of Oncolytics Biotech. "It's a confirmation from the FDA that our design and protocols will support an application for approval and advances pelareorep to be a phase 3 asset. We now look forward to implementation of the Agency’s guidance and to the advancement of pelareorep through this final phase of clinical development."

Final details of the phase 3 clinical trial will be made available at the launch of the study and on www.clinicaltrials.gov.

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 and immuno-therapy and immune modulator (IMiD) combinations to produce innate and adaptive 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, please visit: 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 and mode of action of REOLYSIN®, also known as pelareorep, as a cancer therapeutic; 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 pelareorep as a cancer treatment, the success and timely completion of clinical studies and trials, the Company's ability to successfully commercialize pelareorep, 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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