Oncolytics Biotech® Announces Positive Clinical Trial Results for Pelareorep in Patients with KRAS Mutant Metastatic Colorectal Cancer for Presentation at ESMO 2018

- Pelareorep more than doubles overall survival at recommended phase two doses compared to historical phase 3 data -

CALGARY, Alberta and SAN DIEGO, Oct. 22, 2018 (GLOBE NEWSWIRE) -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC), currently developing pelareorep, an intravenously delivered immuno-oncolytic virus turning cold tumors hot, today announced positive clinical trial results for pelareorep in the treatment of patients with KRAS mutant metastatic colorectal cancer. Patients receiving treatment with the recommended phase 2 dose (RPTD) of pelareorep (“Reo”) in combination with FOLFIRI/B (irinotecan, fluorouracil, leucovorin, plus bevacizumab) had progression free survival (PFS) of 65.6 weeks and an overall survival (OS) of 107.5 weeks, which exceeded expectations when compared to historical data. Engagement of the adaptive immune system was also noted, suggesting that pelareorep promotes an inflamed tumor phenotype. This clinical data was presented at the annual European Society for Medical Oncology (ESMO) 2018 Congress, taking place October 19-23 in Munich.

“The results from the six patients in this study receiving the recommended phase two dose demonstrate a more than doubling of overall survival based on previous phase three studies using FOLIRI with anti-VEGF therapy,” said lead author, Dr. Sanjay Goel, M.D., Department of Medical Oncology, Montefiore Medical Center. “These favorable results lend support to pelareorep as a potential treatment option in this patient population with metastatic disease, that has shown disease progression on current standard-of-care chemotherapy.”

Poster Presentation at ESMO 2018
The poster titled “Dose finding and safety study of Reovirus (Reo) with irinotecan/fluorouracil/leucovorin/bevacizumab (FOLFIRI/B) in patients with KRAS mutant metastatic colorectal cancer (mCRC): Final Results”, was presented yesterday at ESMO. This phase 1 dose escalation study enrolled 36 patients with oxaliplatin refractory KRAS mutant metastatic colorectal cancer. The trial was designed to determine the maximum tolerated dose and a RPTD.

Highlights from the Poster:
Of the six patients receiving the RPTD, three had a partial response (50%) and the median PFS and OS were 65.6 weeks and 107.5 weeks, respectively, exceeding expectations when compared to historical data.

Reovirus administration is marked by activation of cytotoxic T-cells and rapid maturation of dendritic cells.

Reovirus is safe and well tolerated in combination with FOLFIRI and Bevacizumab.

“This impressive survival data coupled with the engagement of the adaptive immune system reinforce both the data from our metastatic breast cancer program and the increasing interest in studies combining pelareorep with immune checkpoint inhibitors," said Dr. Matt Coffey, President and Chief Executive Officer of Oncolytics Biotech. “The results presented at ESMO suggest the clinical utility of pelareorep may expand into multiple indications, including breast, colon and other cancers, and support our clinical development program.”

Additional details can be found on the company website: https://www.oncolyticsbiotech.com/technology/posters-publications.

References:

- Journal of Oncology, Vol. 30, Number 28, October 1, 2012

About Pelareorep

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 and has been demonstrated to be able to escape neutralizing antibodies found in patients.

About Oncolytics Biotech Inc.

Oncolytics is a biotechnology company developing 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 conducting and planning additional studies in combination with checkpoint inhibitors and targeted and IMiD therapies in solid and hematological malignancies, as it prepares for a phase 3 registration study in metastatic breast cancer. 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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