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Oncolytics Biotech® Announces First Patient Treated in Study Combining Pelareorep, Carfilzomib and the Checkpoint Inhibitor Opdivo® in Multiple Myeloma

CALGARY, Alberta and SAN DIEGO, Dec. 12, 2018 (GLOBE NEWSWIRE) -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC), currently developing pelareorep, an intravenously delivered immuno-oncolytic virus, today announced that the first patient was treated in a phase 1 dose escalation study combining pelareorep and carfilzomib with Bristol-Myers Squibb's checkpoint inhibitor Opdivo® (nivolumab) to treat relapsed multiple myeloma patients. This study is based on findings from the NCI 9603 multiple myeloma study that combined pelareorep with carfilzomib that resulted in objective responses, elimination of multiple myeloma cells and most importantly, an inflamed phenotype with PD-L1 overexpression.

"Having worked with pelareorep in multiple myeloma and understanding its ability to act as a potentiator of checkpoint blockade, I'm very excited to work with the Oncolytics team on this study," said Dr. Craig Hofmeister, Associate Professor, Department of Hematology and Medical Oncology Emory University School of Medicine. "Pelareorep has proven its ability to create an inflamed phenotype and its potential for upregulation of PD-1 on tumor-infiltrating lymphocytes. My hope is this study leads not only to an effective combination dosing schedule but provides quantitative data describing the expression of PD-1, along with correlative studies that reveal the roles of both immune-mediated and direct cytotoxic myeloma cell killing."

This open-label, phase 1 study, conducted by Dr. Hofmeister at Emory University, will enroll up to 62 patients to examine the side effects and best dosing schedule of pelareorep when given in combination with dexamethasone, carfilzomib, and nivolumab in treating participants with relapsed multiple myeloma. The primary objectives of the study are to determine the maximum tolerated dose of pelareorep in combination with carfilzomib and nivolumab. Secondary outcome measures include time to progression, progression-free survival and overall survival, as well as the characterization of an inflamed phenotype and confirmation of biomarker responses indicative of tumor inflammation.

"We now have our second checkpoint inhibitor combination study enrolling, and I'm excited for the potential of the immune and biomarker data to come from it," said Dr. Rita Laeufle, Chief Medical Officer of Oncolytics Biotech. "These studies, along with our soon to be initiated studies combining pelareorep with Merck's Keytruda, also in multiple myeloma, and Roche's Tecentriq in neoadjuvant breast cancer, will provide further evidence that pelareorep has the potential to expand the use of checkpoint inhibitors by priming tumors cells. The confirmation of our predictive biomarkers enhances the likelihood of success in registrational studies, thereby reducing both clinical and commercial risk making pelareorep more attractive to potential partners."

For more information about the study, including a comprehensive list of inclusion and exclusion criteria, please visit: www.clinicaltrials.gov (identifier: NCT03605719).

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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