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Oncolytics Biotech® Presents Positive Interim Safety Update from Phase 2 Triple-Negative Breast Cancer Trial at the 2021 San Antonio Breast Cancer Symposium

- No safety concerns have been noted in any trial participants

- Trial builds on prior clinical data demonstrating pelareorep's ability to reverse immunosuppressive tumor microenvironments and upregulate PD-L1 expression in breast cancer

SAN DIEGO, Calif. and CALGARY, AB, Dec. 10, 2021 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) announced a positive interim safety update from the investigator-sponsored, phase 2 IRENE trial in a poster presentation at the 2021 San Antonio Breast Cancer Symposium (SABCS).

The IRENE trial is designed to evaluate the safety and efficacy of pelareorep in combination with Incyte's anti-PD-1 checkpoint inhibitor retifanlimab for second- or third-line treatment of patients with metastatic triple-negative breast cancer (TNBC). Safety data from the trial show that the combination has been well-tolerated, as no safety concerns have been noted in any of the five patients enrolled in the trial at the time of reporting. The trial remains ongoing and will continue to enroll patients at the Rutgers Cancer Institute of New Jersey and the Ohio State University Comprehensive Cancer Center.

Mridula George, M.D., Medical Oncologist, Rutgers Cancer Institute of New Jersey, Assistant Professor of Medicine, Rutgers Robert Wood Johnson Medical School, and principal investigator of the trial commented, "Checkpoint inhibitors benefit only a minority of TNBC patients due to immunosuppressive tumor microenvironments (TMEs) and poor PD-L1 expression. Prior clinical studies have shown that pelareorep upregulates tumor PD-L1 expression and reverses immunosuppressive TMEs. These findings suggest that pelareorep can address a pressing unmet need in TNBC by synergizing with PD-1 inhibition to increase

the proportion of patients responding to therapy. We look forward to evaluating this hypothesis through the IRENE study's continued advancement and are pleased that the pelareorep-retifanlimab combination has been well-tolerated in each of the patients enrolled in the trial."

In addition to evaluating the safety and efficacy of pelareorep plus retifanlimab, IRENE is also designed to assess changes in PD-L1 expression and correlations between treatment outcomes and changes in peripheral blood T cell populations. This could provide a potential biomarker of pelareorep response that may enable the success of future registrational trials by allowing for the early identification of patients most likely to respond to therapy.

A copy of the SABCS poster titled, "*IRENE study: Phase 2 study of Retifanlimab and the oncolytic virus pelareorep in metastatic triple negative breast cancer,*" will be available on the *Posters & Publications* page of Oncolytics' website (LINK) following the conclusion of the symposium.

About IRENE

The IRENE (INCMGA00012 and the oncolytic virus pelareorep in metastatic triple-negative breast cancer) study is a single-arm, open-label, phase 2 study evaluating the combination of pelareorep and Incyte's anti-PD-1 checkpoint inhibitor retifanlimab (INCMGA00012) for the second- or third-line treatment of unresectable locally advanced or metastatic triple-negative breast cancer. The study will enroll 25 patients and is being conducted at the Rutgers Cancer Institute of New Jersey and The Ohio State University Comprehensive Cancer Center.

Study participants will receive pelareorep intravenously on days 1, 2, 15, and 16 of 28-day treatment cycles. Retifanlimab will be administered on day 3 of each cycle, with treatment cycles continuing until disease progression is observed. The co-primary endpoints of the study are safety and objective response rate. Secondary endpoints include progression-free survival, overall survival, and duration of response. Exploratory endpoints include peripheral T cell clonality and pre- vs. post-treatment change in tumor PD-L1 expression.

For more information on the IRENE study, refer to https://clinicaltrials.gov/ct2/show/NCT04445844.

About Oncolytics Biotech Inc.

Oncolytics is a biotechnology company developing pelareorep, an intravenously delivered immunotherapeutic agent. This compound induces anti-cancer immune responses and promotes an inflamed tumor phenotype -- turning "cold" tumors "hot" -- through innate and adaptive immune responses to treat a variety of cancers.

Pelareorep has demonstrated synergies with immune checkpoint inhibitors and may also be synergistic with other approved oncology treatments. Oncolytics is currently conducting and planning clinical trials evaluating pelareorep in combination with checkpoint inhibitors and targeted therapies in solid and hematological malignancies as it advances towards a 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 contained in this press release include statements regarding Oncolytics' belief as to the potential and benefits of pelareorep as a cancer therapeutic; Oncolytics' expectations as to the purpose, design, outcomes and benefits of its current or pending clinical trials involving pelareorep; and other statements related to anticipated developments in Oncolytics' business and technologies. In any forward-looking statement in which Oncolytics expresses an expectation or belief as to future results, such expectations or beliefs are expressed in good faith and are believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will be achieved. Such forward-looking statements involve known and unknown risks and uncertainties, which could cause Oncolytics' 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, Oncolytics' 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. In particular, we may be impacted by business interruptions resulting from COVID-19 coronavirus, including operating, manufacturing supply chain, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption, and shutdowns (including as a result of government regulation and prevention measures). It is unknown whether and how Oncolytics may be affected if the COVID-19 pandemic persists for an extended period of time. We may incur expenses or delays relating to such events outside of our control, which could have a material adverse impact on our business, operating results and financial condition. Investors should consult Oncolytics' 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 any obligation to update these forward-looking statements, except as required by applicable laws.

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