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Oncolytics Biotech® and SOLTI Present New Clinical Biomarker Data Demonstrating Pelareorep's Potential to Improve the Prognosis of Breast Cancer Patients at the ESMO Breast Cancer Meeting

Pelareorep treatment resulted in a favorable Risk of Recurrence Score (ROR-S) in 100% of evaluable patients compared to 55% at baseline in a window-of-opportunity study

Statistically significant increases in markers of tumor cell death and T cell activation observed following treatment with pelareorep-based combinations

SAN DIEGO and CALGARY, AB, May 4, 2022 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) and SOLTI-Innovative Cancer Research today announced new clinical biomarker data demonstrating pelareorep's immunotherapeutic effects, synergy with checkpoint inhibition, and potential to improve the outlook for patients with HR+/HER2- breast cancer. The data, which are featured in a poster presentation at the 2022 European Society for Medical Oncology (ESMO) Breast Cancer Meeting, are from cohorts 1 and 2 of the AWARE-1 window-of-opportunity study in early-stage breast cancer patients.

Patients in AWARE-1's first two cohorts were treated with pelareorep and the aromatase inhibitor letrozole without (cohort 1), or with (cohort 2), the PD-L1 checkpoint inhibitor atezolizumab approximately 21 days prior to the surgical resection of their tumors. Cohorts 1 and 2 of AWARE-1 exclusively enrolled patients with HR+/HER2- disease, the breast cancer subtype that Oncolytics intends to examine in a future registrational study. Previously reported results showed AWARE-1 met its primary translational endpoint, with cohort 2 achieving the pre-specified success criteria for treatment-induced increases in CelTIL score (link to the PR). CelTIL score is a metric for tumor inflammation and cellularity and is

associated with improved clinical outcomes in breast cancer patients.

"The latest data from AWARE-1 further demonstrate pelareorep's potential to improve clinical outcomes in breast cancer patients through its ability to activate T cells and remodel the tumor microenvironment," said Thomas Heineman, M.D., Ph.D., Chief Medical Officer of Oncolytics. "Notably, pelareorep treatment increased markers of tumor cell death and, perhaps even more impressive, 100% of evaluable pelareorep-treated patients had a favorable Risk of Recurrence Score (ROR-S) compared to 55% at baseline. Together, these latest AWARE-1 results further establish pelareorep's ability to attack tumors through multiple mechanisms."

Key data and conclusions from the ESMO Breast Cancer poster include:

- Gene expression analyses showed 100% of evaluable patients had a Risk of Recurrence Score (ROR-S) classified as "low" at surgery vs. 55% with a "low" ROR-S at baseline (information pertaining to prognostic testing of gene signature assays in breast cancer can be found by clicking here)
- Treatment with pelareorep with (cohort 2) or without (cohort1) atezolizumab led to the conversion of tumors from the more aggressive luminal B to the luminal A subtype, which is associated with improved clinical outcomes
    - 100% of evaluable cohort 2 tumors were luminal A at surgery (21 days post-treatment) vs. 70% at baseline (pre-treatment)
    - 70% of evaluable cohort 1 patients had luminal A tumors at surgery vs. 40% at baseline
- Pooled analysis of tumors from cohorts 1 and 2 shows a statistically significant 4-fold post-treatment increase in the average expression of caspase 3, which is a marker of apoptotic cell death
- Pooled analysis across cohorts 1 and 2 shows statistically significant increases in markers of T cell activation and no significant changes in markers of T cell exhaustion from baseline to surgery

Dr. Matt Coffey, President and Chief Executive Officer of Oncolytics Biotech Inc., commented, "AWARE-1's results continue to exceed our expectations. With each new dataset, we gain additional clarity on how pelareorep's immunologic mechanism of action synergistically combines with checkpoint inhibition. The study has also identified changes in blood T cell populations as a potential biomarker to predict patient response. We are now working to confirm these promising findings with efficacy data and additional biomarker analyses from our ongoing BRACELET-1 trial. If positive, we expect BRACELET-1's results to inform the design of a registrational study in HR+/HER2- breast cancer and validate our broader strategy of developing pelareorep in combination with leading anti-cancer agents."

BRACELET-1 is a randomized phase 2 trial in HR+/HER2- metastatic breast cancer. The trial includes cohorts evaluating paclitaxel monotherapy, paclitaxel plus pelareorep, and paclitaxel plus pelareorep in combination with a checkpoint inhibitor. Top-line data from the trial are expected in Q4 2022.

The poster, entitled, *The oncolytic virus pelareorep primes the tumor microenvironment for checkpoint blockade therapy in early breast cancer patients - Results from AWARE-1 study*, is being presented during the "Biomarkers and translational research and precision medicine" session of the ESMO Breast Cancer Meeting. Following the conclusion of the

meeting, the poster will be available on the *Posters & Publications* page of Oncolytics' website (LINK).

About AWARE-1

AWARE-1 was an open-label window-of-opportunity study in early-stage breast cancer. The study combined pelareorep, without or with atezolizumab, and the standard of care therapy according to breast cancer subtype. Tumor tissue was collected from patients as part of their initial breast cancer diagnosis, again on day three following initial treatment, and finally at three weeks following treatment, on the day their tumor is surgically resected. Key objectives of the study were to confirm that pelareorep is acting as a novel immunotherapy, to evaluate potential synergy between pelareorep and checkpoint blockade, and to collect biomarker data. The primary endpoint of the translational study was overall CelTIL score (a measurement of cellularity and tumor-infiltrating lymphocytes). Secondary endpoints for the study included safety and tumor and blood-based biomarkers.

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; our plans to confirm our findings with efficacy data and additional biomarker analyses from our ongoing BRACELET-1 trial; our expectations that positive results from the BRACELET-1 trial may inform the design of a registrational study in HR+/HER2- breast cancer and validate our broader strategy of developing pelareorep in combination with leading anti-cancer agents; the anticipated timing of receipt of top-line data from the trial are expected in Q4 2022; our plans to advance towards a registration study in metastatic breast cancer; 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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