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# Oncolytics Biotech(R) Announces Preliminary AWARE-1 Trial Data Demonstrating Viral Replication and Promotion of Inflammation Following Systemic Administration of Pelareorep When Combined with Tecentriq(R)

***Favorable Steering Committee Recommendation for AWARE-1***

***Early data indicate that T cell clonality may support the development of a biomarker in breast cancer***

**SAN DIEGO, CA and CALGARY, AB / ACCESSWIRE / July 23, 2019 /** Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC), currently developing pelareorep, an intravenously delivered immuno-oncolytic virus, today announced completion of the three patient run-in for the AWARE-1 study in early-stage breast cancer combining pelareorep and Tecentriq® (atezolizumab). All three patients demonstrated immunohistochemically positive viral replication in the tumor mass - two of the three patients showed greater than 50% of the tumor cells infected - following intravenous administration, generating inflammation and T cell recruitment at the tumor site. Increases in PD-L1 expression on tumor cells were noted in all patients, and early data suggest a correlation between T cell clonality and viral replication with highly infected tumors. Importantly, no additional side effects were observed with the combination of pelareorep and atezolizumab beyond those observed for each agent individually.

“Data from the Tecentriq safety run-in support our hypothesis that pelareorep can enhance tumor inflammation not only in HR+/HER2- patients but also in triple-negative breast cancer patients, and we are pleased with the favorable recommendation from the Steering Committee to advance into the next phase of the AWARE-1 study,” said Rita Laeufle, Chief Medical Officer of Oncolytics Biotech. “Importantly, our previously identified biomarker of higher peripheral T cell clonality appears to correlate with patients having the most productive viral infection. As the study continues, we expect data will provide further evidence of the role of pelareorep enhancing the inflammatory process and synergizing with checkpoint blockade.”

“These observations are supportive of our previous findings of improved survival in metastatic breast cancer patients which will allow us to further refine our phase three registration study,” said Dr. Matt Coffey, President, and CEO of Oncolytics Biotech. “While we have previously demonstrated tumor targeting following systemic delivery in the

metastatic setting, these data provide the first evidence that pelareorep can be effectively delivered intravenously and target primary breast cancer. The implications for the treatment of breast cancer in multiple settings and with immune and targeted therapies are vast. We hope to announce interim data at a scientific conference before the end of the year."

**About AWARE-1**

AWARE-1 is an open label window-of-opportunity study in early stage breast cancer that will enroll 38 patients into five cohorts:

- Cohort 1 (n=10), HR+ / HER2- (pelareorep + letrozole)
- Cohort 2 (n=10), HR+ / HER2- (pelareorep + letrozole + atezolizumab)
- Cohort 3 (n=6), TNBC (pelareorep + atezolizumab)
- Cohort 4 (n=6), HR+ / HER2+ (pelareorep + trastuzumab + atezolizumab)
- Cohort 5 (n=6), HR- / HER2+ (pelareorep + trastuzumab + atezolizumab)

The study combines the standard of care by breast cancer subtype with pelareorep and atezolizumab. Patients are biopsied on day one followed immediately by treatment, then again on day three, and a final biopsy after three weeks, on the day of their mastectomy. Data generated from this study is intended to confirm that the virus is acting as a novel immunotherapy and to provide comprehensive biomarker data by breast cancer sub-type. The primary endpoint of the study is overall CelTIL (a measurement of cellularity and tumor-infiltrating lymphocytes). Secondary endpoints for the study include CelTIL by breast cancer subtype, safety and tumor, and blood-based biomarkers.

The study is being coordinated by Dr. Aleix Prat, Head of Medical Oncology at the Hospital Clínic of Barcelona, Associate Professor of the University of Barcelona and the Head of the Translational Genomics and Targeted Therapeutics in Solid Tumors Group at August Pi i Sunyer Biomedical Research Institute (IDIBAPS) and member of Oncolytics' Scientific Advisory Board.

**About Breast Cancer**

Breast cancer is the most common cancer in women worldwide, with over two million new cases diagnosed in 2018, representing about 25 percent of all cancers in women. Incidence rates vary widely across the world, from 27 per 100,000 in Middle Africa and Eastern Asia to 85 per 100,000 in Northern America. It is the fifth most common cause of death from cancer in women globally, with an estimated 522,000 deaths.

Breast cancer starts when cells in the breast begin to grow out of control. These cells usually form a tumor that can often be seen on an x-ray or felt as a lump. The malignant tumor (cancer) is getting worse when the cells grow into (invade) surrounding tissues or spread (metastasize) to distant areas of the body.

**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. Pelareorep has demonstrated synergies with immune checkpoint inhibitors and may also be synergistic with other approved immuno-oncology agents. Oncolytics is currently conducting and planning additional studies in combination with checkpoint inhibitors and targeted 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 plans to co-develop pelareorep in combination with paclitaxel and atezolizumab and the anticipated sharing of costs associated therewith; the Company's AWARE-1 study and the anticipated design, enrollment and timing thereof; the Company's other development plans for pelareorep; the Company's belief as to the potential and mode of action of 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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