

Oncolytics Biotech® Reports Fourth Quarter and Full Year 2019 Financial Results and Operational Highlights

Management hosting conference call and webcast today at 5:00 pm ET

SAN DIEGO and CALGARY, Alberta, March 5, 2020 /PRNewswire/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC), currently developing pelareorep, an intravenously delivered immuno-oncolytic virus, today announced its financial results and operational highlights for the quarter and year ended December 31, 2019. All dollar amounts are expressed in Canadian currency unless otherwise noted.



"As we implemented our focused clinical development and investor relations strategies during 2019, our market valuation and trading volume experienced significant increases," said Kirk Look, Chief Financial Officer at Oncolytics. "Since the middle of the fourth quarter and into 2020, we have leveraged multiple prudent and effective financing strategies, while maintaining trading volume and share price. As of today, with cash of \$29.7 million, our financial runway takes us to the middle of 2021, fully funding our 2020 program and a considerable set of catalysts, including multiple clinical data announcements."

"During 2019, we successfully delivered on our strategy to engage pharma as we laid the groundwork for a catalyst rich 2020 and 2021," said Dr. Matt Coffey, President and CEO of Oncolytics Biotech. "We engaged industry leaders, including Pfizer, Roche, Merck, EMD Serono and BMS, to establish relationships and support four of our five ongoing clinical studies in which we combine pelareorep with checkpoint inhibitors. While we continue to focus on demonstrating the effectiveness of pelareorep in patients with metastatic breast cancer, parallel efforts by large pharma seek to use pelareorep to enhance the efficacy and broaden the application of their immune checkpoint inhibitors. Indeed, we are hopeful that our biomarker strategy, along with our distinct competitive advantages of intravenous delivery and excellent safety profile, makes pelareorep an attractive therapy to boost the range and potency of checkpoint inhibitors commercialized by multiple large pharma

Select highlights from 2019 and early 2020

Breast Cancer Program

- We announced a co-development agreement with Pfizer and EMD Serono to run BRACELET-1, a study of pelareorep in combination with paclitaxel and avelumab (Bavencio[®]), for the treatment of hormone-receptor positive, human epidermal growth factor 2-negative (HR+ / HER2-) metastatic breast cancer. The phase 2 study objective is to confirm the biomarker of T cell clonality, to demonstrate that pelareorep is acting as an immunotherapy and to evaluate the ability of pelareorep to make tumors immunologically visible to checkpoint inhibitors. Costs will be shared by Oncolytics and Pfizer.
- We announced that PrECOG, a leading cancer research network running multiple immuno-oncology trials, will run the BRACELET-1 study, with lead investigator Kathy Miller, MD, Ballve-Lantero Professor of Oncology at Indiana University School of Medicine and Associate Director of Clinical Research at Indiana University Melvin and Bren Simon Cancer Center, and PrECOG member.
- We commenced enrollment in the AWARE-1 window of opportunity study and presented clinical data from the safety run-in at the Society of Immunotherapy for Cancer conference. Viral replication was demonstrated to be exclusively in tumor tissue and created an increase in inflammatory cells through the expansion of existing T cell clones, as well as the creation of new T cell clones. Data also demonstrated that pelareorep changes the immunogenetic environment within the tumor, and to date, the results of this early-stage breast cancer study support the use of T cell clonality as a biomarker that may be able to predict tumor response.

Multiple Myeloma Program

- We presented data from multiple myeloma study NCI-9603 at the 6^{ft} Annual Meeting & Exposition of the American Society of Hematology. Data demonstrated synergies between pelareorep and the proteasome inhibitor carfilzomib through inflammation, apoptosis and tumor responses, including the expansion of CD8+ killer T cells and confirmed the selectivity of pelareorep, which infected multiple myeloma cells while leaving normal bone marrow cells alone.
- We announced highlights from a Key Opinion Leader call featuring Dr. Craig Hofmeister of Winship Cancer Institute at Emory University and Dr. Flavia Pichiorri of the Judy and Bernard Briskin Center for Multiple Myeloma at City of Hope, demonstrating that carfilzomib promotes pelareorep infection by suppressing the innate antiviral response and suggested that the combination does not interfere with T cell activation. It was also noted that pelareorep infection, not proteasome inhibition, can upregulate PD-L1 expression on myeloma cells and the adaptive immune system can then assist in clearing infected tumor cells.

Biomarker

 We announced clinical data from REO 024 in pancreatic cancer at the American Association for Cancer Research Annual Meeting demonstrating the potential utility of T cell clonality as a predictive and prognostic biomarker of pelareorep therapy. Measured with a simple blood draw, the biomarker will allow physicians to understand which patients are likely to respond to treatment. Higher T cell clonality at baseline correlates with longer progression free survival (HR=0.05, p=0.01) and overall survival (HR=0.12, p=0.01) demonstrating the predictive value of the assay and enhanced T cell clonality after the first cycle of treatment correlates with improved overall survival (HR=0.08, p=0.01) and serves as an on-treatment prognostic biomarker.

- We hosted a key opinion leader meeting with investors and analysts to discuss the emerging role of biomarkers and oncolytic viruses in the treatment of cancer, featuring Dirk Arnold, MD, PhD, Executive Board Member of the European Society of Medical Oncology (ESMO) and Chief of Oncology at Asklepios Klinik Altona
- We announced statistically significant data identifying CEACAM6 as a prospective biomarker for pelareorep in the treatment of pancreatic cancer. Data in the presentation associate low levels of the gene CEACAM6 with prolonged progression free survival (PFS) in pelareorep treated patients with pancreatic cancer. PFS increased over 80%, from 5.72 months to 10.32 months (p=0.05). Oncolytics is now working with industry and academic institutions to verify the findings not only in pancreatic cancer but potentially in other GI indications where this biomarker is linked to clinical outcomes.

Additional Scientific Collaborations: Future Opportunities

• Academic collaborators presented preclinical data at IOVC on the synergies between pelareorep and the CDK4/6 inhibitor Ibrance[®], suggesting pelareorep synergizes with CDK4/6 inhibitors by blocking cellular signaling pathways and releasing more double-stranded RNA into the tumor cell, triggering immunogenic cell death, resulting in another effective way to engage the innate and adaptive immune systems. These results, supported by AWARE-1 results in early-stage breast cancer, as well as pelareorep's demonstrated memory/vaccination effect, which may result in these patients not having a disease recurrence, highlight the potential for pelareorep to be an integral component across the breast cancer treatment spectrum. From early-stage breast cancer through to advanced metastatic disease.

Corporate Updates

Mr. Leonard Kruimer, MBA, CPA, joined the Oncolytics' Board of Directors. His
financing, partnering and M&A experience will be invaluable as Oncolytics advances
towards a transformational partnership leading into a phase 3 registrational study in
metastatic breast cancer.

Anticipated Milestones

- AWARE-1 breast cancer study interim safety data: Q1 2020
- Initiate phase 2 BRACELET-1 study in HR+ / HER2- mBC: Q1 2020
- AWARE-1 breast cancer study interim biomarker data: Q2 2020
- Multiple myeloma study (NCI-9603) interim data (ASCO)*: Q2 2020
- Phase 2 second line pancreatic cancer study interim data (ASCO)*: Q2 2020
 - Phase 2 second line pancreatic cancer study final data*: 2H 2020
 - AWARE-1 breast cancer study final biomarker data: 2H 2020

- Multiple myeloma study (Opdivo® combination) interim data (ASH)*: Q4 2020
- Phase 2 BRACELET-1 metastatic breast cancer study interim safety update: Q4 2020
- Complete enrollment in BRACELET-1 metastatic breast cancer study: Q1 2021
- Phase 2 BRACELET-1 metastatic breast cancer study final data: 2H 2021

Financial

- As at December 31, 2019, the company reported \$14.1 million in cash and cash equivalents.
- Operating expense for the fourth quarter of 2019 was \$4.1 million and \$9.6 million for the year 2019, compared to \$2.4 million in the fourth quarter 2018 and \$7.2 million for the year 2018.
- R&D expense for the fourth quarter of 2019 was \$2.8 million and \$11.1 million for the year 2019, compared to \$2.5 million in the fourth quarter 2018 and \$9.4 million for the year 2018.
- Net cash used in operating activities for the fourth quarter of 2019 was \$7.3 million and \$19.9 million for the year 2019 compared to \$4.4 million for the fourth quarter 2018 and \$11.9 million for the year 2018.
- The consolidated net loss for the fourth quarter of 2019 was \$19.4 million compared to \$4.8 million in the fourth quarter 2018. The net loss for the fourth quarter of 2019 reflected a \$12.5 million non-cash change in fair value of warrant derivative compared to nil for the fourth quarter of 2018. The consolidated net loss for the year 2019 was \$33.1 million or \$1.50 per share compared to \$17.0 million or 1.06 per share for the year 2018. The net loss for the year 2019 reflected a \$12.6 million non-cash change in fair value of warrant derivative compared to nil in the year 2018. The warrants issued in connection with our August 2019 public offering are required to be treated as a financial instrument and are revalued at each exercise date and reporting period. Gains and losses resulting from the revaluation are non-cash, do not impact our cash flow and are recorded as a change in fair value of warrant derivative.
- As at March 5, 2020, the Company had approximately \$29.7 million in cash and cash equivalents, an unlimited number of authorized common shares with 37,375,025 common shares issued and outstanding, 16,443,500 warrants (exercisable into 1,730,894 common shares) issued in 2017 with a \$9.025 strike price, 538,938 warrants issued in 2019 with a US\$0.90 strike price and 2,474,491 options and share units.

Webcast and Conference Call

Management will host a conference call for Analysts and Institutional Investors at 5:00 pm ET, today, Thursday, March 5, 2020. The live call may be accessed by dialing 1-888-231-8191 for callers in North America. Overseas callers should contact investor relations for the toll-free dial information for their country. A replay of this call will be available approximately two hours after the call is ended at +1-855-859-2056, using the replay code 3119607 and will be available for one week.

A live webcast of the call will be accessible on the Investor Relations page of Oncolytics' website at www.oncolyticsbiotech.com and will be archived for three months.

^{*}Guidance provided by clinical investigators

About Pelareorep

Pelareorep is a non-pathogenic, proprietary isolate of the unmodified reovirus: a first-in-class intravenously delivered immuno-oncolytic dsRNA virus in development 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"). Forwardlooking statements, including 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 forwardlooking statements, except as required by applicable laws.

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