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Oncolytics Biotech(R) Reports 2019 Second Quarter Financial Results and Operational Highlights

Co-development agreement with Pfizer and Merck KGaA to evaluate Oncolytics' systemically delivered oncolytic virus, pelareorep, in combination with paclitaxel and anti-PD-L1 antibody avelumab

SAN DIEGO, CA and CALGARY, AB / ACCESSWIRE / August 13, 2019/ 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 ended June 30, 2019. All dollar amounts are expressed in Canadian currency unless otherwise noted.

“Oncolytics remains focused on advancing our highly differentiated, systemically delivered oncolytic virus platform, which has generated multiple big pharma partnership opportunities on the back of an established clinical proof-of-concept, as the only viral agent to show a survival benefit in late-stage metastatic breast cancer,” said Dr. Matt Coffey, President and CEO of Oncolytics Biotech. “This quarter we secured a landmark co-development agreement with Pfizer and Merck KGaA to run BRACELET-1 in order to confirm our positive randomized phase two results in metastatic breast cancer and investigate if the addition of their checkpoint inhibitor Bavencio can add to the doubling of overall survival benefit we’ve seen with the virus. We believe this latest and most committed collaboration to date represents pharma’s growing interest in exploring the ability of our first-in-class, systemically delivered oncolytic virus to augment the effects of a range of immune checkpoint inhibitors. It also demonstrates the growing interest in our biomarker development, which we initially presented at this year’s American Association for Cancer Research annual meeting in April, where we presented evidence of a biomarker that has the potential to predict which patients are likely to respond to pelareorep even before we begin treatment, and to confirm the response as quickly as three weeks posttreatment. The clinical development impact of this can be significant, as the biomarker will allow us to better select patients for our clinical trials and to stratify the treatment populations within each protocol based on the biomarker outcome. This would result in more cost-efficient and faster-enrolling trials, with a greater likelihood of success. We also experienced a positive impact on business development, including our co-development agreement with Pfizer and Merck KGaA, as well as additional growing interest from pharma and big biotech. While we intend to expand into additional, commercially valuable indications, including other co-therapies with the checkpoint inhibitor class of drugs, we’ve continued to advance our lead clinical program in breast cancer. We remain on track to report interim safety and primary endpoint biomarker data from the AWARE-1 study in the fourth quarter of 2019 and initiate BRACELET-1 in the first quarter of 2020.”

Select highlights since April 1, 2019

Clinical & Scientific Updates

- Announced phase 2 study (BRACELET-1) to investigate pelareorep in combination with paclitaxel and anti-PD-L1 antibody avelumab in hormone-receptor positive, human epidermal growth factor 2-negative (HR+ / HER2-) metastatic breast cancer in collaboration with Pfizer and Merck KGaA
- Initiated and announced preliminary safety run-in data from the AWARE-1 window of opportunity study, which is being conducted in collaboration with SOLTI, in which patients will receive the appropriate intervention for their breast cancer sub-type plus pelareorep with or without Roche's anti PD-L1 Tecentriq®, followed by surgery
- Announced the identification of a biomarker and initial data at the 2019 American Association for Cancer Research (AACR), demonstrating that patients treated with pelareorep in combination with chemotherapy and pembrolizumab showed changes in their T cell repertories with high turnover and significant expansion, including new T cell clones, during treatment
- Highlighted additional immune biomarker analyses during the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting demonstrating that pelareorep-induced T cell expansion and upregulation of pro-inflammatory genes was durable and correlated with patient survival
- 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

Financial

- At June 30, 2019, the company reported $12.3 million in cash and cash equivalents
- As at August 2, 2019, the company had an unlimited number of authorized common shares with 20,390,316 common shares issued and outstanding, 16,443,500 warrants exercisable into 1,730,894 common shares with a $9.025 strike price and 1,580,611 options and share units
- Operating expense for the second quarter of 2019 was $1.8 million compared to $1.6 million in the second quarter 2018
- Research and development expense for the second quarter of 2019 was $3.5 million compared to $2.0 million in the second quarter 2018
- The net loss for the second quarter of 2019 was $5.3 million compared to $4.2 million in the second quarter 2018, which equates to a loss of $0.26 per share in 2019 compared to a net loss of $0.27 per share in 2018, on a consolidated basis

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.

Company Contact:
Michael Moore
Vice President, Investor Relations & Corporate Communications
858-886-7813
mmoore@oncolytics.ca

Investor Relations
Timothy McCarthy
LifeSci Advisors
212.915.2564
tim@lifesciadvisors.com

Media Contact
Jason Spark
Canale Communications

619-849-6005
jason@canalecomm.com

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