

March 8, 2019



# Oncolytics Biotech (R) Announces 2018 Year-End Results and Operational Highlights

***- Recent biomarker data identifies a simple blood test that may predict clinical response to pelareorep -***

***- AWARE-1 window of opportunity study in breast cancer to begin enrollment in the coming weeks with data expected in the second half of 2019 -***

***- Combination studies with checkpoint inhibitors are evaluating biomarker data and support progression into registration pathway for metastatic breast cancer -***

***- Management to host webcast and conference call today at 8:30 a.m. ET -***

**CALGARY, AB and SAN DIEGO, CA / ACCESSWIRE / March 8, 2019/** Oncolytics Biotech<sup>®</sup> 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, 2018. All dollar amounts are expressed in Canadian currency unless otherwise noted.

"With a growing number of large pharma collaborations, continued advancement with our registration program in metastatic breast cancer and recently announced biomarker data, we have made tremendous progress in a short period of time," said Dr. Matt Coffey, President and CEO of Oncolytics Biotech. "In 2019 we expect to generate data that will allow us to finalize our registration program in breast cancer, while at the same time advancing studies in indications with prior evidence of clinical activity, as defined by an inflamed phenotype. With the global market for checkpoint inhibitors expected to reach \$25 billion in 2022 and checkpoint inhibitors only able to treat approximately twenty percent of patients, the data demonstrating pelareorep's ability to create an inflamed phenotype and boost PD-L1 expression makes it a potential backbone for this drug class. Furthermore, we believe pelareorep can potentially expand the utility of checkpoint inhibitors into additional indications and this work is already underway with Merck's Keytruda in both multiple myeloma and pancreatic cancer, Bristol-Myers Squibb's Opdivo in multiple myeloma and Roche's Tecentriq in breast cancer."

## **Selected highlights since January 1, 2018**

### ***Clinical & Scientific Updates***

- Received confirmation from the FDA and EMA that only a single phase 3 study is

required for approval

- Granted a Special Protocol Assessment (SPA) from the FDA
- Advised to identify a biomarker prior to the final study design
- Announced a Master Clinical Supply Agreement (MCSA) with F. Hoffmann-La Roche Ltd (Roche) to supply Tecentriq<sup>®</sup> for use in the company's clinical development program
- Announced an abstract identifying a potentially predictive and prognostic biomarker to be presented at the 2019 American Association for Cancer Research Annual Meeting
- Entered into a clinical collaboration with SOLTI, a world-leading cooperative group specializing in breast cancer, to conduct our AWARE-1 window of opportunity breast cancer study, to confirm the utility of our recently identified biomarker
  - Marks the first use of our MCSA with Roche
- Presented data highlighting increased expression of PD-L1 on multiple myeloma cells in patients treated with pelareorep at the 2018 American Society of Hematology Annual Meeting, leading to our phase 1b combination study with Bristol-Myers Squibb's Opdivo<sup>®</sup> in multiple myeloma
- Presented data suggesting efficacy signal in combination with PD-1 inhibitor at the Gastrointestinal Cancers Symposium sponsored by ASCO, leading to a phase 2 combination study with Merck's Keytruda<sup>®</sup> in second line pancreatic cancer
- Presented data at the European Society for Medical Oncology 2018 Congress highlighting patients with KRAS mutant metastatic colorectal cancer who were treated with pelareorep and FOLFIRI/Bevacizumab had progression-free survival of 65.6 weeks and overall survival of 107.5 weeks, exceeding expectations when compared to analogous historical data
- Initiated additional clinical collaborations:
  - Pelareorep plus Merck's checkpoint inhibitor Keytruda in pancreatic cancer
  - Pelareorep plus Bristol-Myers Squibb's checkpoint inhibitor Opdivo in multiple myeloma
  - Pelareorep plus Merck's checkpoint inhibitor Keytruda in multiple myeloma
- Announced a publication in *Cancer Immunology Research* demonstrating that intravenously administered pelareorep effectively targets tumors even in the presence of neutralizing antibodies

### **Corporate Updates**

- Announced the appointment of Dr. Rita Laeufle, M.D., Ph.D., as Chief Medical Officer
  - Dr. Laeufle brings more than 15 years of experience in oncology drug development, having previously served at Coherus Biosciences, Clovis Oncology, Roche, Genentech and Novartis
- Announced the listing of the company's shares of common stock on the Nasdaq Capital Market and commenced trading on June 1, 2018, under the symbol "ONCY"
- Closed an underwritten public share offering of 1,532,278 common shares at a purchase price of USD \$5.83 for gross proceeds of approximately USD \$8.9 million
- Announced a USD \$30.0 million At-the-Market facility with Canaccord Genuity LLC
- Entered into a common stock purchase agreement for up to USD \$26.0 million with

## Lincoln Park Capital Fund, LLC

### ***Anticipated Milestones***

- Initiate AWARE-1 in the coming weeks
- Initiate combination study with Merck's Keytruda in multiple myeloma in mid-2019\*
- Data from AWARE-1 study in the second half of 2019
- Prepare for registration study with pelareorep in mBC after AWARE-1 data is available

\* *Guidance provided by principal investigator*

### ***Financial***

- At December 31, 2018, the company reported \$13.7 million in cash and cash equivalents
- As at March 7, 2019, the company had an unlimited number of authorized common shares with 18,840,010 common shares issued and outstanding, 16,443,500 warrants exercisable into 1,730,894 common shares with a \$9.025 strike price and 1,569,326 options and share units
- Operating expense for the fourth quarter of 2018 was \$2.4 million and \$7.2 million for the year 2018, compared to \$2.2 million in the fourth quarter 2017 and \$6.2 million for the year 2017
- R&D expense for the fourth quarter of 2018 was \$2.5 million and \$9.4 million for the year 2018, compared to \$2.5 million in the fourth quarter 2017 and \$9.4 million for the year 2017
- The net loss for the fourth quarter of 2018 was \$4.8 million and \$17.0 million for the year 2018, compared to \$4.7 million in the fourth quarter 2017 and \$15.6 million for the year 2017, which equates to a loss of \$1.06 per share in 2018 compared to a net loss of \$1.12 per share in 2017, on a consolidated basis

### **Webcast and Conference Call**

Management will host a conference call for Analysts and Institutional Investors at 8:30 a.m. ET, today, Friday, March 8, 2019. The live call may be accessed by dialing (877) 407-9205 for callers in North America. Overseas callers should contact investor relations for the toll-free dial information for their country. A live webcast of the call will be accessible on the Investor Relations page of Oncolytics' website at [www.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com) and will be archived for three months. A replay of the call will be available approximately two hours after the call has ended at (877) 481-4010, using the replay code 44902 and will remain available for one week.

### **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](http://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 belief as to the potential and mode of action of REOLYSIN, also known as 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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