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Oncolytics Biotech® Announces Statistically Significant Data Identifying CEACAM6 as a Prospective Prognostic Biomarker for Pelareorep in the Treatment of Pancreatic Adenocarcinoma

Over 80% improvement in progression free survival in patients with low levels of CEACAM6

SAN DIEGO and CALGARY, Alberta, Jan. 27, 2020 /PRNewswire/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC), currently developing pelareorep, an intravenously delivered immuno-oncolytic virus, today announced that a poster presentation highlighting statistically significant data identifying CEACAM6 as a prospective biomarker for pelareorep in the treatment of pancreatic cancer. The presentation was delivered at the 2020 Gastrointestinal Cancers Symposium sponsored by ASCO in San Francisco.

"We have identified another biomarker candidate for pelareorep," said Dr. Rita Laeufle, Chief Medical Officer of Oncolytics Biotech. "These results correlate CEACAM6 levels with long term benefit in patients with pancreatic cancer. We are working with industry and academic colleagues to verify this important finding not only in pancreatic cancer but potentially in other GI indications where this biomarker is linked to clinical outcomes."

The poster, *CEACAM6 is a candidate biomarker for Reolysin® (pelareorep) sensitivity in pancreatic adenocarcinoma (PDAC)*, highlights data from the randomized study NCI 8601: *Carboplatin and Paclitaxel With or Without Viral Therapy in Treating Patients With Recurrent or Metastatic 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).

"I am very encouraged to see additional data come from this important study by the Ohio State University Comprehensive Cancer Center," said Dr. Matt Coffey, President and Chief Executive Officer of Oncolytics Biotech. "This statistically significant result highlights the potential for CEACAM6 to become an additional prognostic biomarker for pelareorep and could provide considerable clinical value as we investigate its potential in pancreatic and other GI cancers."

CEACAM6 is differentially expressed in pancreatic adenocarcinoma cells. High levels of CEACAM6 are known to block viral trafficking in virally infected cells, thereby decreasing viral replication. Study investigators speculated that altered CEACAM6 levels may be

predictive for pelareorep sensitivity and may serve as a biomarker.

Key data and conclusions:

- CEACAM6 was the most differentially expressed gene, with an eight-fold decrease in levels of mRNA, in long-term responders compared to early progressors in patients receiving pelareorep.
- Low levels of CEACAM6 mRNA expression were associated with prolonged PFS in pelareorep-treated patients ($p=0.05$). This treatment effect was not seen in patients that were not treated with pelareorep ($p=0.35$).
- In pelareorep treated patients, CEACAM6 mRNA expression level was very influential with a hazard ratio of 1.54 ($p=0.01$), suggesting that one unit increase in CEACAM6, corresponds to an increase in the risk of progression and/or death by 54% in this arm. There was no significant relationship seen in patients that were not treated with pelareorep
- CEACAM6 may be included as a candidate biomarker of resistance to pelareorep and, in theory, could inhibit viral trafficking in tumor cells

The poster presentation was co-authored by Dr. Anne Noonan, Department of Medical Oncology, Ohio State University Wexner Medical Center, Richard Solove Research Institute and James Cancer Hospital, and Dr. Tanios Bekaii-Saab Senior Associate Consultant, Division of Hematology/Oncology, Department of Internal Medicine, Mayo Clinic, Phoenix, Arizona. It can be found on the *Posters & Publications* page of the company's website: <https://www.oncolyticsbiotech.com/technology/posters-publications>

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 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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📄 View original content: <http://www.prnewswire.com/news-releases/oncolytics-biotech-announces-statistically-significant-data-identifying-ceacam6-as-a-prospective-prognostic-biomarker-for-pelareorep-in-the-treatment-of-pancreatic-adenocarcinoma-300993449.html>

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