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# **Oncolytics Biotech® Announces Publication of Pelareorep's Clinical Benefit Against KRAS Mutated Colorectal Cancer**

**93.3% clinical benefit rate**

**86% improvement over historical overall survival rates at recommended phase 2 dose**

**Pelareorep stimulates robust antitumor adaptive immune response**

SAN DIEGO and CALGARY, Alberta, April 2, 2020 /PRNewswire/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC), currently developing pelareorep, an intravenously delivered immuno-oncolytic virus, today announced positive clinical data published in a peer-reviewed journal highlighting that the combination of FOLFIRI, bevacizumab and pelareorep was well tolerated, with promising efficacy signals in colorectal cancer patients with KRAS mutated tumors. The article, entitled "Elucidation of Pelareorep Pharmacodynamics in a Phase I Trial in Patients with KRAS Mutated Colorectal Cancer," authored by Dr. Sanjay Goel, Department of Medical Oncology, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY, et al., was published on March 10, 2020, in *Molecular Cancer Therapeutics*.

The study enrolled 36 patients with KRAS mutation in a dose-escalation trial, of which 30 patients were assessable for response. The combination of FOLFIRI, bevacizumab and pelareorep was well tolerated, with promising signals of efficacy. Six patients received the recommended phase 2 dose (RP2D), at which a 50% overall response rate and a median overall survival (OS) of 25.1 months were observed, which compares favorably to the historical OS of 13.5 months (an 86% improvement). Among 30 evaluable patients, 6 (20%) had a partial response (PR) and 22 patients (73.3%) had stable disease (SD) as their best response, for a clinical benefit rate (PR +SD) of 93.3%.

Enhanced efficacy elicited by the administration of pelareorep was supported by evidence of an adaptive immune response occurring after each cycle of pelareorep treatment. Rapid maturation of dendritic cells was observed at 48 hours, from a baseline mean of 4.5% to a mean of 18.6% (4.1 fold change,  $p=0.000016$ ), followed by an increase in absolute CD8 (2.4 fold change,  $p=0.00015$ ) and CD4 (3.5 fold change,  $p=0.00015$ ), on day 4. The most important observation was the activation of CD8 cells (CD8+ CD70+) on day 8, from a baseline mean of 1.5% to a mean of 18.8% (12.9 fold change,  $p=0.0009$ ). These dramatic immune responses were only seen after pelareorep administration and not with the other medications alone, strongly suggesting that pelareorep is influencing these responses. In addition, on-treatment tumor biopsies revealed replicating virus (pelareorep), thereby

demonstrating successful and efficient intravenous (systemic) delivery.

"Pelareorep combined with FOLFIRI, bevacizumab triggers a robust adaptive immune response, highlighting a unique pattern of dendritic cell maturation followed by CD8 T cell activation that was observed after every dose of pelareorep," said Dr. Rita Laeufle, Chief Medical Officer at Oncolytics Biotech. "Importantly, we have received great interest from key opinion leaders who are eager to work with pelareorep in gastrointestinal cancers, and this paper supports that interest. Our biomarkers of T cell clonality and CEACAM6, along with these promising efficacy findings, have allowed us to craft a clear clinical strategy in gastrointestinal cancers, and we look forward to providing updates on those plans in the near future."

*Molecular Cancer Therapeutics, a monthly medical journal published by the American Association for Cancer Research, Inc. (AACR), strives to be the top choice for publishing the best science in the discovery and preclinical development of novel therapeutic agents for oncology. A copy of the paper can be found on our 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](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 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. In particular, we may be impacted by business interruptions resulting from COVID-19 coronavirus, including operating, manufacturing supply chain, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures). It is unknown whether and how the Company may be affected if the COVID-19 pandemic persists for an extended period of time. We may incur expenses or delays relating to such events outside of our control, which could have a material adverse impact on our business, operating results and financial condition. 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  
Investor Relations & Corporate Communications  
+1-858-886-7813  
[mmoore@oncolytics.ca](mailto:mmoore@oncolytics.ca)

**Investor Relations for  
Oncolytics**

Timothy McCarthy  
LifeSci Advisors  
+1-212-915-2564  
[tim@lifesciadvisors.com](mailto:tim@lifesciadvisors.com)

 View original content:<http://www.prnewswire.com/news-releases/oncolytics-biotech-announces-publication-of-pelareoreps-clinical-benefit-against-kras-mutated-colorectal-cancer-301033724.html>

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