

March 5, 2021



# Oncolytics Biotech® Reports Fourth Quarter and Full Year 2020 Financial Results and Operational Highlights

- *New clinical data highlight pelareorep's potential to boost the effectiveness of checkpoint inhibitors*
- *Clinical demonstration of pelareorep reversing immunosuppressive tumor microenvironments*
- *On track to report clinical biomarker and safety data in breast cancer in 2021*
- *Strong financial foundation with approximately \$50 million in cash on hand and cash runway to H2 2022*
- *Management hosting conference call and webcast today at 8:30 am ET*

SAN DIEGO and CALGARY, AB, March 5, 2021 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced its financial results and operational highlights for the quarter and year ended December 31, 2020. All dollar amounts are expressed in Canadian currency unless otherwise noted.



"We are beginning 2021 with strong momentum, bolstered by a robust clinical data set that demonstrates the potential of pelareorep to boost the effectiveness of immuno-oncology agents and address major unmet medical needs across multiple indications," said Dr. Matt Coffey, President and Chief Executive Officer of Oncolytics Biotech Inc. "Interim AWARE-1 results highlight pelareorep's ability to train the immune system to target tumors and its potential to synergistically combine with checkpoint blockade therapy in HR+/HER2- breast cancer patients. These findings reinforce the survival benefit observed in our prior phase 2 study and are suggestive of a successful outcome with our phase 2 BRACELET-1 trial, which evaluates pelareorep-checkpoint inhibitor therapy in the same breast cancer subtype. We look forward to reporting additional biomarker and safety data from our lead breast

cancer program later this year and to the program's continued advancement towards a registrational study."

Dr. Coffey continued, "Beyond our lead program, we continue to leverage our compelling data and collaborations with industry leaders to expand pelareorep's commercial and business development potential. Pelareorep promotes tumor inflammation and upregulates PD-L1 expression in the clinic, positioning it to address unmet needs in triple-negative breast cancer (TNBC) and gastrointestinal (GI) cancers. In each of these indications, checkpoint inhibitors have had commercial success, but immunosuppressive tumor microenvironments (TMEs) and low PD-L1 expression severely limit their efficacy and the number of patients who can be successfully treated. Through our IRENE and GOBLET trials, we are collaborating with industry leaders to show that we can increase the percentage of TNBC and GI cancer patients responding to checkpoint blockade by taking advantage of pelareorep's immunotherapeutic effects. Excitingly, pelareorep's synergistic benefits appear to extend to immunomodulatory agents beyond checkpoint inhibitors, as recent preclinical results show that pelareorep may broaden the applicability of CAR T cells to solid tumors by improving their persistence and efficacy. Looking ahead, we will explore a partnership strategy to develop pelareorep as an enabling technology for CAR T cells and other immunotherapies while keeping our primary focus on our lead breast cancer program. We believe this strategy will drive and expand our sustained growth by allowing for the efficient development of pelareorep in a variety of difficult-to-treat indications. Finally, with our strengthened financial position, we look forward to accelerating these activities and delivering on our catalysts."

## **Select highlights from 2020 and early 2021**

### **Breast Cancer Program**

#### ***Reported AWARE-1 Data Demonstrating Pelareorep's Ability to Reverse Immunosuppressive TMEs and Potential to Boost the Effectiveness of Checkpoint Inhibitors***

AWARE-1 data presented at the 2020 San Antonio Breast Cancer Symposium (SABCS) showed that systemic pelareorep treatment increased tumor PD-L1 expression by an average of 105-fold in early-stage breast cancer patients, thereby making tumors more amenable to checkpoint inhibitor therapy. Data also showed that 72% of patients saw an increase in CeITIL (the study's primary endpoint), a measure of tumor-associated cellularity and tumor-infiltrating lymphocytes that is associated with favorable clinical response. These data add to prior AWARE-1 results showing that systemic pelareorep treatment led to the generation of new anti-viral and anti-tumor T cell clones and an average 14-fold increase in intratumoral CD8+ T cells. Together, these data support the results of a prior successful phase 2 trial ([IND-213](#)) that showed a near doubling of overall survival with pelareorep treatment by demonstrating pelareorep's ability to induce robust and potentially long-lasting anti-tumor immune responses in HR+/HER2- breast cancer patients ([link](#) to PR, [link](#) to poster).

#### ***Initiated Dosing in Phase 2 BRACELET-1 Study and Successfully Completed Safety Run-in***

Oncolytics advanced its lead breast cancer program with the initiation of dosing in

BRACELET-1, a randomized phase 2 study being conducted under a co-development agreement with Merck KGaA (Darmstadt, Germany) and Pfizer. BRACELET-1 is designed to generate mechanistic data supporting the results of [IND-213](#) and to evaluate pelareorep's ability to synergistically combine with anti-PD-L1 therapy. The study also seeks to validate peripheral T cell clonality as a biomarker of pelareorep response in HR+/HER2- metastatic breast cancer, which may improve the patient selection process in future registration studies and increase their likelihood of success. The trial's safety run-in has been successfully completed, with the Data and Safety Monitoring Board verifying pelareorep's outstanding safety profile.

### ***Initiated Dosing in Phase 2 IRENE Study***

Oncolytics expanded its lead breast cancer program into a new disease subtype through the initiation of dosing in IRENE, a phase 2 investigator-sponsored study investigating the use of pelareorep in combination with Incyte's anti-PD-1 checkpoint inhibitor retifanlimab (INCMGA00012) in patients with unresectable locally advanced or metastatic TNBC. In addition to investigating the safety and efficacy of pelareorep-anti-PD-1 combination treatment in TNBC patients, the study also evaluates changes in PD-L1 expression and correlations between treatment outcomes and peripheral T cell clonality.

### **Gastrointestinal Cancer Program**

#### ***Announced Phase 1/2 GOBLET Study in Collaboration with Roche and AIO***

GOBLET is a phase 1/2 multi-center trial designed to investigate the use of pelareorep in combination with Roche's anti-PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®) in patients with metastatic pancreatic, metastatic colorectal and advanced anal cancers. The trial is being managed by AIO, a leading academic cooperative medical oncology group based in Germany. GOBLET builds on previously reported early clinical data showing that pelareorep-based combination treatments stimulated an adaptive immune response and led to a greater than 90% clinical benefit rate in KRAS mutated colorectal cancer patients ([link to PR](#), [link to study](#)), as well as a greater than 80% increase in progression-free survival (PFS) in pancreatic cancer patients with low levels of CEACAM6 expression ([link to PR](#), [link to poster](#)). In addition to evaluating the safety and efficacy of pelareorep-atezolizumab treatment, the trial also seeks to validate CEACAM6 and T cell clonality as predictive biomarkers, which may improve the patient selection process in future registration studies and increase their likelihood of success.

### **Hematologic Malignancies Program**

#### ***Announced Clinical Proof-of-Concept Data at the ASCO Virtual Meeting***

Phase 1b data presented at the American Society of Clinical Oncology (ASCO) meeting showed that pelareorep, when combined with carfilzomib, activated a profound inflammatory response accompanied by a 50% overall response rate and an 83% clinical benefit rate in patients with challenging-to-treat carfilzomib-refractory multiple myeloma ([link to the PR](#), [link to the poster](#)). The data also showed the first reported incidence of cytokine stimulation associated with tumor response in multiple myeloma, highlighting the ability of pelareorep to induce robust immune cell activation and tumor lysis. Together with earlier trial data showing pelareorep-induced upregulation of PD-L1 expression, these data

highlight the potential of pelareorep to synergistically combine with checkpoint inhibitors in hematologic cancers.

## **Opportunities to Further Expand the Clinical Benefits of Pelareorep to Additional Indications**

### ***Reported Positive Clinical Results Against Glioblastoma Multiforme***

Oncolytics announced positive results from ReoGlio, an investigator-sponsored phase 1b trial evaluating the combination of pelareorep and granulocyte-macrophage colony-stimulating factor (GM-CSF) alongside standard chemoradiotherapy and adjuvant temozolomide for the treatment of glioblastoma multiforme (GBM) at the 2020 Society of Neuro-Oncology Annual Meeting ([link](#) to the PR). The results showed a compelling signal of efficacy and demonstrated the safety and tolerability of the pelareorep-based combination therapy in newly diagnosed GBM patients. Notably, observed improvements in median PFS correlated with the dose of pelareorep administered. Oncolytics thanks the University of Leeds, Cancer Research UK, and The Brain Tumor Charity for designing, managing, and funding the ReoGlio trial.

### ***Demonstrated the Potential of Pelareorep to Broaden the Applicability of CAR T Cells to Solid Tumors***

A recent preclinical study from the Mayo Clinic showed that loading chimeric antigen receptor (CAR) T cells with pelareorep vastly improved their persistence and efficacy in a murine solid tumor model, in stark contrast to preclinical studies using intratumoral infection with the VSV oncolytic virus that weakened CAR T cells ([link](#) to the PR, [link](#) to the poster). The efficacy of pelareorep-loaded CAR T cell ("CAR/Pela") therapy was further enhanced by boosting mice 8 days later with a single intravenous dose of pelareorep, which led to the generation of highly persistent CAR T cells, the inhibition of recurrent tumor growth, and ultimately tumor cures. These synergistic immune effects were specific to pelareorep, as intravenous boosting with VSV did not augment CAR/Pela therapy or prevent the growth of recurrent tumors. Together, these data demonstrate the potential of pelareorep to broaden the applicability of CAR T cells to solid tumors, an area where CAR T cell efficacy is currently limited due to immunosuppressive TMEs that promote T cell exhaustion and exclusion.

## **Corporate Highlights**

### ***Appointed Richard Vile, Ph.D., to Scientific Advisory Board***

Dr. Vile, a Professor of Immunology at the Mayo Clinic, is a world-renowned scientist and long-time collaborator of Oncolytics with extensive experience studying pelareorep, and led the Mayo Clinic CAR T preclinical study mentioned above. Dr. Vile is a recognized key opinion leader whose research focuses on several areas of immuno-oncology, including oncolytic viruses, adoptive cell therapies (ACTs) such as CAR T cells, and potential synergistic interactions between oncolytic viruses and ACTs. In addition to his role as a professor at the Mayo Clinic ("Mayo"), Dr. Vile is the Director of Mayo's Immuno-oncology and Gene and Virus Therapy programs and Co-Director of the Cancer Immunology and Immunotherapy program. He also serves on the editorial board of several prestigious scientific journals, including Molecular Therapy, Gene Therapy, The Journal of Gene Medicine, and OncoImmunology.

## ***Financial Highlights***

- As at December 31, 2020, the Company reported \$31.2 million in cash and cash equivalents. The Company raised gross proceeds of \$40.0 million during 2020 through the issuing of common stock through our ATM facility.
- Operating expense was \$4.0 million for the fourth quarter of 2020 and \$12.5 million for the full year 2020, compared to \$4.1 million in the fourth quarter of 2019 and \$9.6 million for the full year 2019.
- R&D expense was \$4.1 million for the fourth quarter of 2020 and \$12.9 million for the full year 2020, compared to \$2.7 million in the fourth quarter of 2019 and \$10.8 million for the full year 2019.
- Net cash used in operating activities was \$5.7 million for the fourth quarter of 2020 and \$22.1 million for the full year 2020, compared to \$7.3 million in the fourth quarter of 2019 and \$19.9 million for the full year 2019.
- The net loss for the fourth quarter of 2020 was \$9.3 million, compared to a net loss of \$19.4 million in the fourth quarter of 2019. The basic and diluted loss per share was \$0.21 in the fourth quarter of 2020, compared to a basic and diluted loss per share of \$0.71 in the fourth quarter of 2019. The net loss for the full year 2020 was \$22.5 million, compared to a net loss of \$33.1 million for the full year 2019. The basic and diluted loss per share was \$0.56 for the full year 2020, compared to a basic and diluted loss per share of \$1.50 for the full year 2019.
- As at March 4, 2021, the Company had approximately \$50 million in cash and cash equivalents, an unlimited number of authorized common shares with 52,083,924 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, 110,572 warrants issued in 2020 with a US\$0.90 strike price and 3,878,852 options and share units.

## **Anticipated Milestones & Catalysts**

- Announcement of final data from phase 2 NU 18101 second-line pancreatic cancer study\*: H1 2021
- Dosing of the first patient in GOBLET study in gastrointestinal cancer: H1 2021
- Interim data for AWARE-1 breast cancer study: H1 2021
- Final biomarker data for AWARE-1 breast cancer study in the intended target population for a registrational study: H2 2021
- Interim safety update from Phase 2 BRACELET-1 metastatic breast cancer study: H2 2021
- Completion of enrollment in BRACELET-1 metastatic breast cancer study: Q4 2021

- Interim safety update from IRENE study in TNBC: Q4 2021
- Interim safety data from phase 1 WINSHIP 4398-18 multiple myeloma study: Q4 2021

*\*Guidance provided by clinical investigators*

Oncolytics expects to provide updates on the timing of the following milestones over the coming months:

- Phase 2 BRACELET-1 metastatic breast cancer study: final data

## Update on COVID-19

Oncolytics continues to collaborate with its investigators to ensure the safety of patients and employees, as well as the productivity of its clinical programs. We expect these measures will allow us to build on the positive momentum of the past year, despite any COVID-19-related challenges that may arise. Moving forward, we plan to remain in contact with relevant stakeholders and keep the market apprised of any new information that may impact clinical timelines.

## Webcast and Conference Call

Management will host a conference call for analysts and institutional investors at 8:30 am ET today, March 5, 2021. To access the call, please dial (888) 231-8191 (North America) or (647) 427-7450 (International) and, if needed, provide confirmation number 569-6653. A live webcast of the call will also be available by clicking [here](#) or on the Investor Relations page of Oncolytics' website ([LINK](#)) and will be archived for three months. A dial-in replay will be available for one week and can be accessed by dialing (855) 859-2056 (North America) or (416) 849-0833 (International) and using reference code 569-6653.

**ONCOLYTICS BIOTECH INC.**  
**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**  
(in Canadian dollars, except share amounts)

As at December 31,	2020 \$	2019 \$
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	31,219,574	14,148,021
Other receivables	89,661	2,068,772
Prepaid expenses	2,427,200	2,713,591
<b>Total current assets</b>	<b>33,736,435</b>	<b>18,930,384</b>
<b>Non-current assets</b>		
Property and equipment	236,664	296,768
Right-of-use assets	372,468	430,713
<b>Total non-current assets</b>	<b>609,132</b>	<b>727,481</b>
<b>Total assets</b>	<b>34,345,567</b>	<b>19,657,865</b>
<b>Liabilities And Shareholders' Equity (Deficit)</b>		
<b>Current Liabilities</b>		
Accounts payable and accrued liabilities	1,805,015	3,173,218
Other liabilities	123,985	847,215
Lease liabilities	248,885	339,846
Warrant derivative	531,228	8,508,764
<b>Total current liabilities</b>	<b>2,709,113</b>	<b>12,869,043</b>
<b>Non-current liabilities</b>		
Contract liability	6,730,287	6,730,287
Lease liabilities	153,174	166,429
<b>Total non-current liabilities</b>	<b>6,883,461</b>	<b>6,896,716</b>

<b>Total liabilities</b>	<b>9,592,574</b>	19,765,759
<i>Commitments and contingencies</i>		
<b>Shareholders' equity (deficit)</b>		
Share capital		
Authorized: unlimited		
Issued: December 31, 2020 – 46,166,980		
December 31, 2019 – 32,198,453	<b>356,824,172</b>	311,077,859
Warrants	<b>3,617,570</b>	3,617,570
Contributed surplus	<b>31,022,356</b>	29,338,849
Accumulated other comprehensive income	<b>400,225</b>	464,101
Accumulated deficit	<b>(367,111,330)</b>	(344,606,273)
<b>Total shareholders' equity (deficit)</b>	<b>24,752,993</b>	(107,894)
<b>Total liabilities and shareholders' equity (deficit)</b>	<b>34,345,567</b>	19,657,865

**ONCOLYTICS BIOTECH INC.**  
**CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS**  
(in Canadian dollars, except share amounts)

	<b>2020</b>	<b>2019</b>	<b>2018</b>
For the years ending December 31,	\$	\$	\$
<b>Expenses</b>			
Research and development	<b>12,944,510</b>	10,817,997	10,027,994
Operating	<b>12,514,496</b>	9,558,641	7,244,791
<b>Loss before the following</b>	<b>(25,459,006)</b>	(20,376,638)	(17,272,785)
Change in fair value of warrant derivative	<b>3,491,928</b>	(12,608,808)	—
Foreign exchange (loss) gain	<b>(659,173)</b>	(316,719)	610,106
Interest income, net	<b>121,194</b>	179,277	173,496
<b>Loss before income taxes</b>	<b>(22,505,057)</b>	(33,122,888)	(16,489,183)
Income tax expense	—	—	(548,042)
<b>Net loss</b>	<b>(22,505,057)</b>	(33,122,888)	(17,037,225)
<b>Other comprehensive (loss) income items that may be reclassified to net loss</b>			
Translation adjustment	<b>(63,876)</b>	(143,403)	233,774
<b>Net comprehensive loss</b>	<b>(22,568,933)</b>	(33,266,291)	(16,803,451)
<b>Basic and diluted loss per common share</b>	<b>(0.56)</b>	(1.50)	(1.06)
<b>Weighted average number of shares (basic and diluted)</b>	<b>40,338,789</b>	22,137,990	16,016,366

**ONCOLYTICS BIOTECH INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (DEFICIT)**  
(in Canadian dollars)

	Share Capital	Warrants	Contributed Surplus	Accumulated Other Comprehensive Income	Acc I
	\$	\$	\$	\$	
As at December 31, 2017	271,710,138	3,617,900	27,028,238	373,730	(294,4
Net loss and other comprehensive income	—	—	—	233,774	(17,0
Issued pursuant to "At the Market" Agreement	620,010	—	—	—	
Issued pursuant to public offering	11,606,882	—	—	—	
Issued pursuant to Common Stock Purchase Agreement	3,314,097	—	—	—	
Issued pursuant to stock option plan	197,245	—	(73,707)	—	
Issued pursuant to incentive share award plan	109,751	—	(109,751)	—	
Issued pursuant to warrant agreement	1,747	(330)	—	—	
Share-based compensation	—	—	1,415,833	—	
Share issue costs	(2,366,809)	—	—	—	
As at December 31, 2018	285,193,061	3,617,570	28,260,613	607,504	(311,4
Net loss and other comprehensive income	—	—	—	(143,403)	(33,1
Issued pursuant to incentive share award plan	391,917	—	(391,917)	—	

Issued pursuant to Common Stock Purchase Agreement	5,403,385	—	—	—	
Issued pursuant to "At the Market" Agreement	8,476,454	—	—	—	
Issued pursuant to public offering	3,314,429	—	—	—	
Issued pursuant to warrant derivative exercised	9,152,869	—	—	—	
Share-based compensation	—	—	1,470,153	—	
Share issue costs	(854,256)	—	—	—	
<b>As at December 31, 2019</b>	<b>311,077,859</b>	<b>3,617,570</b>	<b>29,338,849</b>	<b>464,101</b>	<b>(344,6</b>
Net loss and other comprehensive income	—	—	—	(63,876)	(22,5
Issued pursuant to stock option plan	385,022	—	(143,100)	—	
Issued pursuant to incentive share award plan	732,367	—	(732,367)	—	
Issued pursuant to "At the Market" Agreement	40,037,786	—	—	—	
Issued pursuant to warrant derivative exercised	6,332,778	—	—	—	
Share-based compensation	—	—	2,558,974	—	
Share issue costs	(1,741,640)	—	—	—	
<b>As at December 31, 2020</b>	<b>356,824,172</b>	<b>3,617,570</b>	<b>31,022,356</b>	<b>400,225</b>	<b>(367,1</b>

**ONCOLYTICS BIOTECH INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in Canadian dollars)

For the years ending December 31,	2020	2019	2018
	\$	\$	\$
<b>Operating Activities</b>			
Net loss for the year	(22,505,057)	(33,122,888)	(17,037,225)
Depreciation - property and equipment	88,957	122,982	95,375
Depreciation - right-of-use assets	357,230	362,592	—
Share-based compensation	2,558,974	1,470,153	1,415,833
Interest expense on lease liabilities	68,526	94,817	—
Unrealized foreign exchange loss (gain)	645,078	353,189	(374,337)
Onerous lease contract	—	—	67,588
Amortization - lease incentive liability	—	—	8,189
Change in fair value of warrant derivative	(3,491,928)	12,608,808	—
Net change in non-cash working capital	209,779	(1,795,777)	3,904,339
<b>Cash used in operating activities</b>	<b>(22,068,441)</b>	<b>(19,906,124)</b>	<b>(11,920,238)</b>
<b>Investing Activities</b>			
Acquisition of property and equipment	(29,305)	(10,905)	(107,466)
<b>Cash used in investing activities</b>	<b>(29,305)</b>	<b>(10,905)</b>	<b>(107,466)</b>
<b>Financing Activities</b>			
Proceeds from exercise of stock options	241,922	—	123,538
Proceeds from exercise of warrants	1,696,460	3,465,867	1,417
Proceeds from Common Stock Purchase Agreement	—	5,360,247	2,533,980
Proceeds from "At the Market" equity distribution agreement	38,296,146	8,131,620	451,675
Proceeds from public offering	—	4,505,359	10,188,526
Payment of lease liabilities	(460,724)	(447,497)	—
<b>Cash provided by financing activities</b>	<b>39,773,804</b>	<b>21,015,596</b>	<b>13,299,136</b>
<b>Increase in cash</b>	<b>17,676,058</b>	<b>1,098,567</b>	<b>1,271,432</b>
Cash and cash equivalents, beginning of year	14,148,021	13,699,881	11,836,119
Impact of foreign exchange on cash and cash equivalents	(604,505)	(650,427)	592,330
<b>Cash and cash equivalents, end of year</b>	<b>31,219,574</b>	<b>14,148,021</b>	<b>13,699,881</b>

## About AWARE-1

AWARE-1 is an open label window-of-opportunity study in early-stage breast cancer enrolling 38 patients into five cohorts:

- Cohort 1 (n=10), HR+ / HER2- (pelareorep + letrozole)
- Cohort 2 (n=10), HR+ / HER2- (pelareorep + letrozole + atezolizumab)



- Cohort 3 (n=6), TNBC (pelareorep + atezolizumab)
- Cohort 4 (n=6), HR+ / HER2+ (pelareorep + trastuzumab + atezolizumab)
- Cohort 5 (n=6), HR- / HER2+ (pelareorep + trastuzumab + atezolizumab)

The study combines pelareorep, with or without atezolizumab, and the standard of care according to breast cancer subtype. Patients are biopsied as part of their initial breast cancer evaluation, then again on day three following initial treatment, and a final tissue sample after three weeks, on the day of their mastectomy. Data generated from this study are intended to confirm that the virus is acting as a novel immunotherapy and to provide comprehensive biomarker data by breast cancer subtype. The primary endpoint of the study is overall CeITIL (a measurement of cellularity and tumor-infiltrating lymphocytes). Secondary endpoints for the study include CeITIL by breast cancer subtype, safety, and tumor and blood-based biomarkers.

For more information about the AWARE-1 study, refer to <https://clinicaltrials.gov/ct2/show/NCT04102618>.

### **About BRACELET-1**

The BRACELET-1 (**BR**east **cAn**CEr with the Oncolytic Reovirus **PeL**areor**Ep** in **Combi**nation with anti- PD-L1 and Paclitaxel) study is an open-label, phase 2, randomized study in patients with HR+/HER2-, endocrine-refractory metastatic breast cancer being conducted under a co-development agreement with [Merck KGaA](#), Darmstadt, Germany and Pfizer. [PrECOG LLC](#), a leading cancer research network, is managing the study. The study will take place at 20 trial sites and enroll 45 patients randomized into three cohorts. A three patient safety run-in will be conducted with patients receiving pelareorep, paclitaxel, and avelumab prior to randomization. The three cohorts will be treated as follows:

- Cohort 1 (n=15): paclitaxel
- Cohort 2 (n=15): paclitaxel + pelareorep
- Cohort 3 (n=18): paclitaxel + pelareorep + avelumab (Bavencio®)

Patients in cohort 1 will receive paclitaxel on days 1, 8, and 15 of a 28-day cycle. Patients in cohort 2 will receive the same paclitaxel regimen as cohort 1, plus pelareorep on days 1, 2, 8, 9, 15 and 16 of the 28-day cycle. Patients in cohort 3 will receive the same combination and dosing regimen as cohort 2, plus avelumab on days 3 and 17 of the 28-day cycle. The primary endpoint of the study is overall response rate. Exploratory endpoints include peripheral and tumor T cell clonality, inflammatory markers, and safety and tolerability assessments.

For more information about the BRACELET-1 study, refer to <https://clinicaltrials.gov/ct2/show/NCT04215146>

### **About IRENE**

The IRENE (INCMGA00012 and the oncolytic virus **pelareorep** in metastatic triple-**neg**ative breast cancer) study is a single-arm, open-label, phase 2 study evaluating the combination

of pelareorep and INCMGA00012 for the treatment of unresectable locally advanced or metastatic triple-negative breast cancer. The study will enroll 25 patients and will be conducted at the Rutgers Cancer Institute of New Jersey and The Ohio State University Comprehensive Cancer Center.

Study participants will receive pelareorep intravenously on days 1, 2, 15, and 16 of 28-day treatment cycles. INCMGA00012 will be administered on day 3 of each cycle, with treatment cycles continuing until disease progression is observed. The co-primary endpoints of the study are safety and objective response rate. Secondary endpoints include progression-free survival, overall survival, and duration of response. Exploratory endpoints include peripheral T cell clonality and pre- vs. post-treatment change in tumor PD-L1 expression.

For more information on the IRENE study, refer to <https://clinicaltrials.gov/ct2/show/NCT04445844>.

### **About GOBLET**

The GOBLET (Gastrointestinal tumors exploring the treatment combinations with the oncolytic reovirus pelareorep and anti-PD-L1) study is a phase 1/2 multiple indication biomarker, safety, and efficacy study in advanced or metastatic GI tumors. The study will be conducted at 25 centers in Germany. The primary endpoint of the study is safety, with overall response rate and blood-based biomarkers (T cell clonality and CEACAM6) as exploratory endpoints. Approximately 55 patients are planned for enrollment across four separate cohorts:

1. Pelareorep in combination with atezolizumab, gemcitabine, and nab-paclitaxel in 1<sup>st</sup> line metastatic Pancreatic cancer patients (n=12);
2. Pelareorep in combination with atezolizumab in 2<sup>nd</sup> and 3<sup>rd</sup> line metastatic colorectal cancer patients that are diagnosed as MSI (microsatellite instability) high (n=19);
3. Pelareorep in combination with atezolizumab and TAS-102 in 3<sup>rd</sup> line metastatic colorectal cancer patients (n=14); and
4. Pelareorep in combination with atezolizumab in 2<sup>nd</sup> line advanced and unresectable anal cancer patients (n=10).

### **About ReoGlio**

The ReoGlio trial was an investigator-sponsored phase 1b, open-label trial evaluating the combination of pelareorep and GM-CSF, alongside standard chemoradiotherapy and adjuvant temozolomide, for the treatment of newly diagnosed GBM. Fifteen patients were treated in the trial, twelve of which were evaluable for efficacy analyses. The primary objective of the study was to determine the maximum tolerated dose of pelareorep and GM-CSF with standard chemoradiotherapy. Secondary objectives were to gain a preliminary assessment of the activity of the pelareorep-GM-CSF combination and to assess treatment compliance. The trial was designed and managed by the University of Leeds and funded through grants provided by Cancer Research UK and The Brain Tumor Charity.

### **About Breast Cancer**

Breast cancer is the most common cancer in women worldwide, with over two million new

cases diagnosed in 2018, representing about 25 percent of all cancers in women. It is the second leading cause of death from cancer in women in America, with an estimated 42,000 deaths in the US in 2020.<sup>1</sup>

Breast cancer starts when cells in the breast begin to grow out of control. These cells usually form a tumor that can often be seen on an x-ray or felt as a lump. The malignant tumor (cancer) is getting worse when the cells grow into (invade) surrounding tissues or spread (metastasize) to distant areas of the body.

### **About Gastrointestinal Cancer**

Excluding skin cancers, colorectal cancer is the third most common cancer, with an estimated 104,610 new cases of colon cancer and 43,340 new cases of rectal cancer diagnosed in the U.S. in 2020<sup>2</sup>. Also, for the 2020 year, the American Cancer Society estimates there will be 57,600 new cases of pancreatic cancer<sup>3</sup> and 8,590 new cases of anal cancer<sup>4</sup> in the U.S.

### **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 of pelareorep 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).

### **References:**

1. "Breast Cancer Statistics And Resources." Breast Cancer Research Foundation. <https://www.bcrf.org/breast-cancer-statistics-and-resources>
2. "Key Statistics for Colorectal Cancer." *The American Cancer Society*, American Cancer Society, Inc., <https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html>
3. "Key Statistics for Pancreatic Cancer." *The American Cancer Society*, American Cancer Society, Inc., <https://www.cancer.org/cancer/pancreatic-cancer/about/key-statistics.html>
4. "Key Statistics for Anal Cancer." *The American Cancer Society*, American Cancer Society, Inc., <https://www.cancer.org/cancer/anal-cancer/about/what-is-key->

[statistics.html](#)

*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, contained in this press release include statements regarding Oncolytics' belief as to the potential and benefits of pelareorep as a cancer therapeutic; Oncolytics' expectations as to the purpose, design, outcomes and benefits of its current or pending clinical trials involving pelareorep; plans respecting the delivery of additional clinical data and the timing thereof; the potential commercial opportunity of pelareorep; Oncolytics' expectations for its various partnerships and collaborations and its strategies for further partnerships and collaborations; Oncolytics' anticipated milestones and catalysts; Oncolytics' objectives, including registration opportunities; Oncolytics' measures to manage the impact of the COVID-19 pandemic on its operations; and other statements related to anticipated developments in Oncolytics' business and technologies. In any forward-looking statement in which Oncolytics expresses an expectation or belief as to future results, such expectations or beliefs are expressed in good faith and are believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will be achieved. Such forward-looking statements involve known and unknown risks and uncertainties, which could cause Oncolytics' 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, Oncolytics' 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 Oncolytics 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 Oncolytics' 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 any obligation to update these forward-looking statements, except as required by applicable laws.*

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