Oncolytics Biotech® Announces Updated Randomized Phase 2 Data from BRACELET-1 Metastatic Breast Cancer Trial that Show Pelareorep Driving Robust Increases in Progression-Free Survival and Confirmed Overall Response Rate

Pelareorep-paclitaxel combination reduced risk of disease progression by 71% (hazard ratio of 0.29) compared to paclitaxel monotherapy

37.5% confirmed overall response rate with pelareorep-paclitaxel vs. 13.3% with paclitaxel monotherapy

12-month progression-free survival rate of 32.8% for pelareorep-paclitaxel compared to 0% for paclitaxel monotherapy and 0% for pelareorep-paclitaxel-avelumab

Oncolytics' HR+/HER2- breast cancer program now phase 3-ready and advancing to a registrational study of pelareorep-paclitaxel combination

Data to be discussed during a key opinion leader webinar today, June 5th at 8:00 a.m. ET (registration link here)

SAN DIEGO and CALGARY, AB, June 5, 2023 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced updated results from BRACELET-1, a randomized phase 2 trial in HR+/HER2- metastatic breast cancer, which include data featured in an oral presentation at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, as well as additional new data and analyses.

BRACELET-1 enrolled 48 patients, including 45 that were randomized and well-balanced
across three cohorts evaluating: (1) paclitaxel monotherapy; (2) paclitaxel in combination with pelareorep; and (3) paclitaxel plus pelareorep in combination with the anti-PD-L1 checkpoint inhibitor, avelumab (Bavencio®). A three-patient safety run-in was also conducted with patients receiving pelareorep, paclitaxel, and avelumab prior to randomization. All participants enrolled in the trial had previously progressed on at least one hormone-based therapy with a CDK 4/6 inhibitor. No patients in BRACELET-1 received chemotherapy for metastatic disease prior to enrolling in the trial.

Updated data from BRACELET-1 showed a median progression-free survival (mPFS) of 9.5 months in the paclitaxel plus pelareorep cohort vs. 6.3 months in the paclitaxel monotherapy cohort for a hazard ratio of 0.29 as of a March 3, 2023 cut-off date. Confirmed overall response rate (ORR) in these cohorts was 37.5% and 13.3%, respectively. As previously reported, ORR at week-16 (the trial's primary endpoint) in the pelareorep plus paclitaxel and paclitaxel monotherapy cohorts was 31.3% and 20%, respectively. Overall survival data from the trial continue to mature.

"BRACELET-1’s positive results complement prior phase 2 data showing a statistically significant increase in overall survival when pelareorep was combined with paclitaxel by demonstrating similar robust improvements in PFS and ORR in less heavily pre-treated patients," said Dr. Matt Coffey, President and Chief Executive Officer. "Given this exciting finding, our next step is to discuss our data with the FDA to investigate incorporating dual PFS and OS endpoints into our breast cancer program's registrational study. Including a PFS endpoint could substantially reduce the time to a pivotal readout from the registrational trial, thereby accelerating pelareorep's path to potential approval as we work to address the urgent needs of HR+/HER2- breast cancer patients."

A summary of response and PFS data from all 48 patients enrolled in BRACELET-1 is shown below.

Additional updated BRACELET-1 data:

<table>
<thead>
<tr>
<th></th>
<th>Paclitaxel (PTX) Monotherapy (n=15)</th>
<th>PTX + Pelareorep (n=16)</th>
<th>PTX + Pelareorep + Avelumab (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirmed ORR Over Course of Trial</td>
<td>2 (13.3 %)</td>
<td>6 (37.5 %)</td>
<td>3 (17.6 %)</td>
</tr>
<tr>
<td>mPFS (months)</td>
<td>6.3 (95% CI: 3.9, NR)</td>
<td>9.5 (95% CI: 6.5, NR)</td>
<td>6.2 (95% CI: 4.0, NR)</td>
</tr>
<tr>
<td>PFS Hazard Ratio vs. PTX Monotherapy</td>
<td>-</td>
<td>0.29 (95% CI: 0.09, 0.98)</td>
<td>1.31 (95% CI: 0.47, 3.65)</td>
</tr>
<tr>
<td>12-month PFS Rate (%)</td>
<td>0 (95% CI: -, -)</td>
<td>32.8 (95% CI: 11.7, 92.4)</td>
<td>0 (95% CI: -, -)</td>
</tr>
</tbody>
</table>

1. Data from a March 3, 2023 cut-off date. Numbers presented may change as they are derived from an unlocked database.
2. Data include all patients enrolled in trial. Response data presented by Clark et al. at ASCO 2023 included the 45 randomized patients and excluded participants in the three-patient safety run-in in cohort 3.

Key biomarker and safety findings from BRACELET-1 include:

- Association between T cell expansion and efficacy measures: A statistically significant increase in T cell fraction, a measure of T cell expansion, was observed in cohort 2 (paclitaxel + pelareorep) but not cohort 3 (paclitaxel + pelareorep + avelumab)
Generally favorable and manageable safety profile: Pelareorep displayed a manageable safety profile consistent with what has been observed in prior clinical trials that have collectively treated over 1,100 patients.

Dr. Thomas Heineman, Chief Medical Officer, commented, "BRACELET-1's impressive initial results are maturing quite favorably. While five patients in the pelareorep-paclitaxel group had partial responses at week 16, six patients in total had confirmed responses. This includes two patients who improved from stable disease to partial responses at later times, consistent with pelareorep's immunologic mechanism of action. Moreover, the compelling ORR and PFS hazard ratio achieved align with translational results showcasing pelareorep's immune-mediated mechanism of action and complement additional data that support the combination therapy's generally favorable safety profile. Collectively, these results bolster an expansive clinical dataset supporting the potential of pelareorep-paclitaxel combination therapy in HR+/HER2- metastatic breast cancer and are expected to propel our program to a pivotal licensure-enabling study."

A copy of slides from the ASCO oral presentation on BRACELET-1, titled 'BRACELET-1 (PrE0113): Inducing an Inflammatory Phenotype in Metastatic HR+/HER2- Breast Cancer with the Oncolytic Reovirus Pelareorep in Combination with Paclitaxel and Avelumab,' is available on the Posters & Publications page of Oncolytics' website (LINK). Additional data and analyses from BRACELET-1 beyond those reported at the ASCO Annual Meeting will be available in the most recent investor presentation available by clicking here. Details of the key opinion leader webinar are shown below.

Key Opinion Leader Webinar

Oncolytics will host a key opinion leader (KOL) webinar featuring Richard Vile, Ph.D., (Mayo Clinic), Aleix Prat, M.D., Ph.D. (Clinic Barcelona), and Martine J. Piccart, M.D., Ph.D. (Université Libre de Bruxelles) today, June 5, 2023 at 8:00 a.m. ET. During the webinar, the KOLs and members of the Oncolytics management will discuss the current treatment landscape for HR+/HER2- metastatic breast cancer, as well as BRACELET-1’s results. A live question and answer session will follow a formal presentation and roundtable discussion with the KOLs. To register for the event, please click here.

About BRACELET-1

The BRACELET-1 (BReast cAnCEr with the Oncolytic Reovirus PeLareorEp in CombinaTion 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. The study randomized 45 patients 1:1:1 into three cohorts. A three-patient safety run-in was also conducted with patients receiving pelareorep, paclitaxel, and avelumab prior to randomization. The three cohorts are treated as follows:

- Cohort 1: paclitaxel
- Cohort 2: paclitaxel + pelareorep
- Cohort 3: paclitaxel + pelareorep + avelumab (Bavencio®)

Patients in cohort 1 receive paclitaxel on days 1, 8, and 15 of a 28-day cycle. Patients in cohort 2 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 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 at week 16. Exploratory endpoints include progression-free survival, peripheral and tumor T cell clonality, inflammatory markers, and safety and tolerability assessments.

About Oncolytics Biotech Inc.

Oncolytics is a biotechnology company developing pelareorep, an intravenously delivered immunotherapeutic agent. This compound induces anti-cancer immune responses 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 multiple approved oncology treatments. Oncolytics is currently conducting and planning combination clinical trials with pelareorep in solid and hematological malignancies as it advances towards registrational studies in metastatic breast cancer and pancreatic 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 contained in this press release include statements regarding Oncolytics' belief as to the potential and benefits of pelareorep as a cancer therapeutic; our plans to discuss our data with the FDA to enable our breast cancer program's expeditious advancement to a registrational study with dual PFS and OS endpoints; the anticipated benefits of including a PFS endpoint in a registrational study; our expectation that the results of our BRACELET-1 study will propel our program to a pivotal licensing-enabling study; our plans to advance towards registrational studies in metastatic breast cancer and pancreatic cancer; 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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