Oncolytics Biotech® Reports Interim Results from Phase 1/2 GOBLET Study Showing a 70% Objective Response Rate in Pancreatic Cancer at the SITC Annual Meeting

70% objective response rate (ORR; n=10) is nearly triple the average ORR of ~25% reported in historical control trials1-4

Data suggest pelareorep synergizes with PD-(L)1 inhibitors and standard-of-care chemotherapy in advanced/metastatic pancreatic ductal adenocarcinoma

Oncolytics plans to present pancreatic cancer data to regulators to determine the most expeditious path to approval

Company management to discuss these results and ongoing efforts to advance pelareorep into registration studies in breast and pancreatic cancer during Q3 earnings call today at 8:30 a.m. ET

Updated data from GOBLET's pancreatic cancer cohort to be presented in a poster at the SITC meeting and discussed during a key opinion leader webinar on November 14th at 10 a.m. ET

SAN DIEGO and CALGARY, AB, Nov. 7, 2022 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today reported interim results from the phase 1/2 GOBLET study’s first-line advanced/metastatic pancreatic ductal adenocarcinoma (PDAC) cohort in an abstract published as part of the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting. The SITC meeting is taking place both virtually and in-person at the Boston Convention and Exhibition Center in Boston, MA, from November 8 – 12, 2022.
As of the abstract's data cutoff date (July 28, 2022), seven of ten evaluable patients in GOBLET's PDAC cohort, which evaluates pelareorep in combination with Roche's anti-PD-L1 checkpoint inhibitor atezolizumab and the chemotherapeutic agents gemcitabine and nab-paclitaxel, achieved a partial response (3 confirmed, 4 unconfirmed as of the cutoff date). An additional two patients achieved stable disease for an ORR and clinical benefit rate of 70% and 90%, respectively. No safety signals were observed with the studied combination.

"The ORR reported in the SITC abstract is remarkably nearly triple the average ORR seen in historical control trials of gemcitabine plus nab-paclitaxel, which is only about 25%," said Dirk Arnold M.D., Ph.D., Director of Asklepios Tumorzentrum Hamburg, and primary investigator of the GOBLET trial. "Further, PD-(L)1 inhibitors only benefit fewer than one percent of pancreatic cancer patients classified as MSI-high. GOBLET's interim results, therefore, strongly suggest that pelareorep's ability to reverse immunosuppressive tumor microenvironments produces synergies when combined with checkpoint inhibition and chemotherapy, leading to vastly improved responses. Given the urgent need for novel therapies in pancreatic cancer, I believe this exciting finding highlights an opportunity for pelareorep to transform the standard of care."

Dr. Matt Coffey, President and Chief Executive Officer of Oncolytics Biotech Inc., commented, "GOBLET's interim results represent a crucial clinical milestone, providing robust proof-of-concept in a difficult-to-treat indication. Our next step is to discuss these data with regulatory authorities and potential partners, with the goal of advancing our pancreatic cancer program into a pivotal study. By adding a second near-term registration opportunity alongside our breast cancer program, we have enhanced pelareorep's value proposition and further de-risked our clinical pipeline. I look forward to discussing the strategic implications of our new data during our earnings call today and to hearing expert perspectives on GOBLET's results at our key opinion leader webinar next week."

Updated results from GOBLET's PDAC cohort, which is designed to enroll twelve evaluable patients, will be presented in a poster at the upcoming SITC meeting. The trial's metastatic colorectal and advanced anal cancer cohorts are proceeding as planned, with the cohort in third-line metastatic colorectal cancer now fully enrolled.

Alongside this potential PDAC opportunity, Oncolytics continues to advance pelareorep towards a registration study in metastatic breast cancer. The company's randomized phase 2 trial in HR+/HER2- metastatic breast cancer, BRACELET-1, remains on track for a readout on overall response rate, progression-free survival, and evolving overall survival data in the first half of 2023.

Additional details related to the SITC abstract and upcoming poster, entitled, *Pelareorep combined with atezolizumab and chemotherapy demonstrates encouraging results as first-line treatment in advanced or metastatic pancreatic ductal adenocarcinoma (PDAC) patients – Interim results from the GOBLET study*, are shown below.

**Abstract Number:** 650

**Poster Session Date and Time:** November 11, 2022 from 9:00 a.m. – 8:30 p.m. ET

**Poster Session Location:** Boston Convention and Exhibition Center, Hall C
A copy of the abstract is currently available for viewing in the *Journal for ImmunoTherapy of Cancer (JITC)* supplement. A copy of the poster will be available on the *Posters & Publications* page of Oncolytics' website ([LINK](#)) following the conclusion of the meeting.

**Earnings Webcast and Conference Call**

The Oncolytics management team will discuss the data published in the SITC abstract and the Company's clinical development strategy in pancreatic cancer during its third quarter earnings call taking place today, November 7, 2022 at 8:30 a.m. ET. To access the call, please dial (888) 664-6383 (North America) or (416) 764-8650 (International) and, if needed, provide confirmation number 4240-6541. 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 (888) 390-0541 (North America) or (416) 764-8677 (International) and using replay code: 406-541#.

**Key Opinion Leader Webinar**

Oncolytics will host a key opinion leader (KOL) webinar on November 14, 2022 at 10 a.m. ET. During the webinar, the KOLs and members of the Oncolytics management team will discuss the current treatment landscape and unmet medical need in pancreatic cancer, as well as the updated interim GOBLET study results that will be presented at the SITC meeting. A live question and answer session will follow the formal presentations.

To register for the webinar, please [click here](#).

**References**


**About GOBLET**

The GOBLET (Gastrointestinal tum*O*rS exploring the treatment comBinations with the oncolytic reovirus peLarEorep and anTi-PD-L1) study is a phase 1/2 multiple indication study in advanced or metastatic gastrointestinal tumors. The study is being conducted at 14 centers in Germany. The co-primary endpoints of the study are objective response rate (ORR) assessed at week 16 and safety. Key secondary and exploratory endpoints include additional efficacy assessments and evaluation of potential biomarkers (T cell clonality and CEACAM6). The study employs a Simon two-stage design with Stage 1 comprising four treatment groups expected to enroll a total of approximately 55 patients:

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

Any cohort showing an ORR above a pre-specified threshold in Stage 1 may be advanced to Stage 2 and enroll additional patients.

About AIO

AIO-Studien-gGmbH (AIO) emerged from the study center of the Internal oncology working group within the German Cancer Society (DKG). AIO operates with a non-profit purpose of promoting science and research with a focus on medical oncology. Since its foundation, AIO has become a successful sponsor and study management company and has established itself both nationally and internationally.

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 immune checkpoint inhibitors and may also be synergistic with other approved oncology treatments. Oncolytics is currently conducting and planning clinical trials evaluating pelareorep in combination with checkpoint inhibitors and targeted therapies in solid and hematological malignancies as it advances towards registration 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 mode of action, potential and benefits of pelareorep as a cancer therapeutic; our plan to discuss our GOBLET data with regulatory authorities and potential partners; our goal of advancing its pancreatic cancer program into a pivotal study; Oncolytics’ belief that pelareorep’s value proposition has been enhanced and that the Company’s clinical program has been further de-risked by virtue of the GOBLET data; the timing of release of updated GOBLET and BRACELET-1 results; our plans to advance towards a registration study 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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