November 10, 2022

Oncolytics Biotech® Presents Updated Clinical Data at SITC Annual Meeting Showing a 69% Objective Response Rate and Confirmed Complete Response in GOBLET Study's Pancreatic Cancer Cohort

One complete response (CR) and eight partial responses (PR) achieved in thirteen evaluable patients

69% objective response rate (ORR) is nearly three times greater than the average ORR of ~25% reported in historical control trials

Data support Oncolytics' plan to advance its pancreatic cancer program into a pivotal study

Data to be discussed during a key opinion leader webinar on November 14th at 10 a.m. ET

SAN DIEGO, Calif and CALGARY, AB, Nov. 10, 2022 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced updated results from the phase 1/2 GOBLET study's first-line advanced/metastatic pancreatic ductal adenocarcinoma (PDAC) cohort. Patients in this cohort are treated with the combination of pelareorep, Roche's anti-PD-L1 checkpoint inhibitor atezolizumab, and the chemotherapeutic agents gemcitabine and nab-paclitaxel. The updated data are featured in a poster presentation at the ongoing Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting, which is taking place both virtually and in-person at the Boston Convention and Exhibition Center in Boston, MA.

Objective response rate (ORR) and clinical benefit rate (CBR) in GOBLET's PDAC cohort (n=13) were 69% and 85%, respectively, as of the SITC poster's data cutoff date (October 12, 2022). **Additional data and conclusions presented in the poster are**

summarized below.

- One of thirteen evaluable patients achieved a confirmed CR
- Eight of thirteen evaluable patients achieved a PR
- Two of thirteen evaluable patients achieved stable disease (SD)
- The observed ORR of 69% is substantially higher than the average ORR of ~25% reported in historical control trials of gemcitabine and nab-paclitaxel in pancreatic cancer[1-4]
- GOBLET's PDAC cohort exceeded the protocol-specified success criterion for Stage 1 of ≥ 3/12 objective responses
- The studied treatment combination has been well tolerated, with no safety concerns identified to date

"GOBLET's interim results indicate pelareorep may be the key to finally improving the standard-of-care for first-line treatment of pancreatic cancer, a clear need given that treatment options have not changed for many years despite their limited benefits," commented Thomas C. Heineman, M.D., Ph.D., Chief Medical Officer of Oncolytics Biotech Inc. "The robust efficacy signal in GOBLET markedly exceeded expectations based on historical results and is especially encouraging as most responding patients had their tumor regressions confirmed by subsequent evaluations. We were particularly excited to see a partial response deepen into a confirmed complete response as of the latest data cut, since this further indicates potentially durable anti-cancer effects from the combination therapy."

Dr. Matt Coffey, President and Chief Executive Officer of Oncolytics Biotech Inc., added, "The impressive results being presented at SITC, together with prior clinical data providing a strong mechanistic rationale for the apparent synergies being displayed by pelareorep, PD-L1 inhibition, and chemotherapy, support our pancreatic cancer program's advancement into a pivotal trial. We look forward to discussions with regulators to enable these efforts and align on the optimal design for a licensure-enabling study. In parallel, we continue to make strong progress with our breast cancer program; and are thrilled to be advancing a pipeline that includes two potentially compelling registration opportunities."

The poster (#650), 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,* will be available for live viewing at the SITC meeting tomorrow, November 11, 2022 from 9:00 a.m. – 8:30 p.m. ET. A copy of the poster will also be available on the *Posters & Publications* page of Oncolytics' website (LINK) following the conclusion of the meeting.

Key Opinion Leader Webinar

Oncolytics will host a key opinion leader (KOL) webinar featuring Dirk Arnold, M.D., Ph.D. (Asklepios Tumorzentrum Hamburg), Andrea Bullock, M.D., MPH (Beth Israel Deaconess Medical Center) and Thomas Seufferlein, M.D., Ph.D. (Ulm University, Germany) 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 being 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

1. Von Hoff D et al. N Engl J Med 2013; 369:1691-1703 DOI: 10.1056/NEJMoa1304369
2. O'Reilly et al. Eur J Cancer. 2020 June; 132: 112–121. DOI:10.1016/j.ejca.2020.03.005
3. Karasic et al. JAMA Oncol. 2019 Jul 1; 5(7):993-998. DOI: 10.1001/jamaoncol.2019.0684
4. Tempero et al. Ann Oncol. 2021 May; 32(5):600-608. DOI: 10.1016/j.annonc.2021.01.070

About GOBLET

The GOBLET (**G**astrointestinal tum**O**rs exploring the treatment com**B**inations with the oncolytic reovirus pe**L**ar**E**orep and an**T**i-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 and is being managed by AIO-Studien-gGmbH. 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 1st line advanced/metastatic pancreatic cancer patients (n=12);
2. Pelareorep in combination with atezolizumab in 1st 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 potential and benefits of pelareorep as a cancer therapeutic; our belief that pelareorep may be the key to finally improving the standard-of-care for first-line treatment of pancreatic cancer; the purpose and design of our ongoing clinical studies; 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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