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Oncolytics Biotech® Provides Positive Safety Update on the Pancreatic Cancer Cohort of its Multi-Indication Phase 1/2 Gastrointestinal Cancer Trial

Independent safety review completed with no toxicity concerns

Cohort builds on prior proof-of-concept data demonstrating clinical benefit of pelareorep-checkpoint inhibitor combination in pancreatic cancer

Multi-indication trial being conducted in collaboration with Roche and AIO also includes cohorts in metastatic colorectal and advanced anal cancers

SAN DIEGO and CALGARY, AB, Feb. 2, 2022 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced the successful completion of the three-patient safety run-in for the pancreatic cancer cohort of the phase 1/2 GOBLET study following evaluation by the study's Data Safety Monitoring Board (DSMB). The DSMB noted no safety concerns in these patients and recommended the study proceed as planned. The safety run-in for the trial's third-line metastatic colorectal cancer cohort remains ongoing.

The GOBLET study is being managed by AIO, a leading academic cooperative medical oncology group based in Germany, and is designed to evaluate the safety and efficacy of pelareorep in combination with Roche's anti-PD-L1 checkpoint inhibitor atezolizumab in patients with metastatic pancreatic, metastatic colorectal, and advanced anal cancers. The study remains ongoing and is expected to enroll patients at 14 clinical trial sites across Germany.

"This positive safety evaluation adds to a robust body of evidence demonstrating the favorable safety profile of pelareorep-checkpoint inhibitor combinations across multiple indications," said Thomas Heineman, M.D., Ph.D., Chief Medical Officer of Oncolytics. "It also represents an important step in the development of these combinations for the treatment of pancreatic cancer and builds on prior clinical proof-of-concept data in this indication. These data highlight the potential of pelareorep to benefit patients with pancreatic and other gastrointestinal cancers by reversing immunosuppressive tumor microenvironments that limit the effectiveness of checkpoint inhibitors. We believe adding pelareorep to treatment regimens will improve clinical response rates in these patients, and we look forward to evaluating this hypothesis through successfully advancing the GOBLET study."

The GOBLET study's pancreatic cancer cohort extends previously reported clinical data demonstrating the synergy and anti-cancer activity of pelareorep combined with checkpoint

inhibition in pancreatic cancer patients who progressed after first-line treatment ([link](#) to PR, [link](#) to poster). It also builds on prior early clinical data that showed a greater than 80% increase in median progression-free survival in pancreatic cancer patients with low levels of CEACAM6 expression who received pelareorep in combination with chemotherapy ([link](#) to PR, [link](#) to poster). In addition to evaluating the safety and efficacy of pelareorep-atezolizumab treatment, GOBLET also seeks to demonstrate the potential of CEACAM6 and T cell clonality as predictive biomarkers, which may increase the likelihood of success of future registrational studies by allowing selection of the most appropriate patients.

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 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 1st line 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 internal oncology. Since its foundation, AIO has become a successful sponsor and study management company and has established itself both nationally and internationally.

About Gastrointestinal Cancer

Excluding skin cancers, colorectal cancer is the third most common cancer, with an estimated 104,270 new cases of colon cancer and 45,230 new cases of rectal cancer expected to be diagnosed in the U.S. in 2021¹. Also, for the 2021 year, the American Cancer Society estimates there will be 60,430 new cases of pancreatic cancer² and 9,090 new cases of anal cancer³ in the U.S.

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 a registration study in metastatic breast cancer. For further information, please visit: www.oncolyticsbiotech.com.

References

1. "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>
2. "Key Statistics for Pancreatic Cancer." *The American Cancer Society*, American Cancer Society, Inc., <https://www.cancer.org/cancer/pancreatic-cancer/about/key-statistics.html>
3. "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; management's expectations as to enrollment in the Company's GOBLET study; 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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