March 31, 2022

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

Independent review identified, no safety concerns in trial's final safety run-in

Cohort supported by prior clinical data showing a pelareorep-based combination driving a 90% clinical benefit rate in KRAS-mutated colorectal cancer patients

Multi-indication trial being conducted in collaboration with Roche and AIO also includes pancreatic and advanced anal cancer cohorts

SAN DIEGO, Calif. and CALGARY, AB, March 31, 2022 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced the successful completion of the three-patient safety run-in for the third-line metastatic colorectal cancer (mCRC) cohort of the phase 1/2 GOBLET study, following an independent review by the study's Data Safety Monitoring Board (DSMB). The DSMB noted no safety concerns in these patients and has recommended that the study proceed to full enrollment pending clearance by the Paul Ehrlich Institute (PEI; Germany's medical regulatory body). The PEI recently cleared the study's pancreatic cancer cohort for full enrollment following a similar recommendation by the DSMB. The trial's anal cancer and first-line mCRC cohorts do not include safety run-ins and are proceeding as planned.

The GOBLET study 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 includes 14 clinical trial sites across Germany and is being managed by AIO, a leading academic cooperative medical oncology group.

"The successful completion of GOBLET's final safety run-in underscores the trial's strong momentum and supports the ability of pelareorep to be safely combined with checkpoint inhibitors," said Thomas Heineman, M.D., Ph.D., Chief Medical Officer of Oncolytics. "This achievement positions us to continue building on prior clinical data that demonstrate the potential of pelareorep to provide a clinical benefit in colorectal and other gastrointestinal (GI) cancers. Existing data suggest this clinical benefit likely results from the stimulation of protective immune responses that may be enhanced by the addition of checkpoint inhibition. Given the high prevalence of GI malignancies, including colorectal and pancreatic cancer, and the fact that most cases do not respond to checkpoint inhibition, we view GOBLET as an important opportunity to evaluate a novel therapeutic approach that may address a pressing unmet medical need."

The GOBLET study's metastatic colorectal cancer cohorts are supported by prior clinical data demonstrating adaptive anti-tumor immune responses and a 90% clinical benefit rate in KRAS-mutated mCRC patients treated with a pelareorep-based combination (link to PR, link to study). In addition to primary endpoints evaluating safety and efficacy, GOBLET also includes exploratory endpoints designed to explore the potential of CEACAM6 and T cell clonality to serve as predictive biomarkers. This may increase the likelihood of success of future registrational studies by allowing for the 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 theinternal 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 estimates indicating that 106,180 new cases of colon cancer and 44,850 new cases of rectal cancer will be diagnosed in the U.S. in 2022[1]. Also, for the 2022 year, the American Cancer Society estimates there will be 62,210 new cases of pancreatic cancer[2] and 9,440 new cases of anal cancer[3] 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, our beliefs regarding the potential of CEACAM6 and T cell clonality to predict patient responses to therapy and improvements to our ability to select patients most likely to respond to pelareorep-based therapies in future trials across multiple indications; our plans to advance towards a registration study in metastatic breast 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.

Company Contact
Jon Patton
Director of IR & Communication
+1-858-886-7813
jpatton@oncolytics.ca

Investor Relations for Oncolytics
Timothy McCarthy
LifeSci Advisors
+1-917-679-9282
tim@lifesciadvisors.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/oncolytics-biotech-provides-positive-safety-update-on-the-third-line-metastatic-colorectal-cancer-cohort-of-its-multi-indication-phase-12-gastrointestinal-cancer-trial-301514611.html

SOURCE Oncolytics Biotech® Inc.