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Oncolytics Biotech® Doses First Patient in Phase 1/2 GOBLET Study Evaluating Pelareorep-anti-PD-L1 Combination Therapies in Gastrointestinal Cancers

- *Multi-center trial is being conducted in collaboration with Roche and AIO*
- *Trial is designed to assess the safety and efficacy of pelareorep-atezolizumab combination therapies across multiple gastrointestinal cancer indications*
- *Trial builds on prior promising data from pancreatic and colorectal cancer trials*

SAN DIEGO and CALGARY, AB, Nov. 3, 2021 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced that the first patient has been dosed in the phase 1/2 GOBLET trial. The trial is being managed by AIO, a leading academic cooperative medical oncology group based in Germany, and is designed to investigate the use of pelareorep in combination with Roche's anti-PD-L1 checkpoint inhibitor atezolizumab in patients with metastatic pancreatic, metastatic colorectal and advanced anal cancers.

"Fewer than half of gastrointestinal (GI) cancer patients respond to immune checkpoint inhibitor (ICI) monotherapy, creating a pressing unmet need for techniques to enhance the efficacy of these agents," said Dirk Arnold M.D., Ph.D., Director of Asklepios Tumorzentrum Hamburg, and primary investigator of the GOBLET trial. "We believe that pelareorep can address this need and increase the proportion of GI cancer patients responding to ICIs, as clinical studies have shown that it reverses the immunosuppressive tumor microenvironments underlying checkpoint inhibitor resistance. Dosing the first patient in GOBLET represents a crucial step towards the evaluation of this hypothesis, and we look forward to the trial's continued advancement."

The GOBLET study builds on data that was recently presented at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting that demonstrated clinical proof-of-concept for pelareorep-checkpoint inhibitor combination therapy in pancreatic cancer ([link](#) to PR, [link](#) to poster). It is also supported by prior early clinical data showing that pelareorep-based combination treatments stimulated an adaptive immune response and led to a greater than 90% clinical benefit rate in KRAS-mutated colorectal cancer patients ([link](#) to PR, [link](#) to study) and a greater than 80% increase in progression-free survival in pancreatic cancer patients with low levels of CEACAM6 expression ([link](#) to PR, [link](#) to poster). In addition to evaluating the safety and efficacy of pelareorep-atezolizumab treatment, the trial also seeks to demonstrate the potential of CEACAM6 and T cell clonality as predictive biomarkers, which may allow selection of the most appropriate patients in future registration studies and increase their likelihood of success.

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 biomarker, safety, and efficacy study in advanced or metastatic gastrointestinal tumors. The study is being conducted at 15 centers in Germany. The primary endpoint of the study is safety, with overall response rate and biomarker evaluation (T cell clonality and CEACAM6) as exploratory endpoints. Approximately 55 patients are planned to be enrolled in four independent cohorts:

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).

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 immuno-oncology agents. 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; 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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[doses-first-patient-in-phase-12-goblet-study-evaluating-pelareorep-anti-pd-l1-combination-therapies-in-gastrointestinal-cancers-301415176.html](https://www.oncolyticsbiotech.com/press-releases/2014/09/01/first-patient-in-phase-12-goblet-study-evaluating-pelareorep-anti-pd-l1-combination-therapies-in-gastrointestinal-cancers-301415176.html)

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