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Oncolytics Biotech® Collaborates with Roche and AIO to Initiate a Phase 1/2 Gastrointestinal Cancer Trial Combining Pelareorep with Roche's Anti-PD-L1 Checkpoint Inhibitor

Multi-center trial to assess the safety and efficacy of pelareorep-atezolizumab combination therapies across multiple GI cancer indications

Treatment aimed at 4.8M global GI cancer cases annually¹ and the approximately 80% of GI cancer patients who do not respond to immune checkpoint inhibitor therapy currently

Study builds on prior early findings of greater than 90% clinical benefit in colorectal and greater than 80% increase in progression-free survival in pancreatic cancer patients

SAN DIEGO, CA and CALGARY, AB, Oct. 27, 2020 /CNW/ -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC) today announced a new multi-indication gastrointestinal (GI) cancer study to be managed by AIO, a leading academic cooperative medical oncology group based in Germany. The phase 1/2 trial, known as GOBLET, will investigate the use of pelareorep, in combination with Roche's anti-PD-L1 checkpoint inhibitor atezolizumab (Tecentriq®), in patients with metastatic pancreatic, metastatic colorectal and advanced anal cancers.



"We are very excited for the opportunity to treat patients with pelareorep, which has the potential to address significant unmet needs across multiple challenging indications with poor prognoses in the GI cancer space," said Dirk Arnold M.D., Ph.D., Director of the Asklepios Tumorzentrum Hamburg, and principal investigator of the newly announced trial. "Despite the great commercial success of checkpoint inhibitors, as many as four in five patients do not respond to these therapies in most GI malignancies, often due to an immunosuppressive tumor microenvironment (TME). We believe that pelareorep treatment

may substantially increase the proportion of patients who are eligible for, and respond to, checkpoint inhibitor therapy. Prior clinical data in breast, hematological, and also some early data in gastrointestinal cancers have shown that systemic pelareorep administration reverses immunosuppressive TMEs by increasing tumor immune cell infiltration and PD-L1 expression."

Thomas Heineman, M.D., Ph.D., Global Head of Clinical Development and Operations at Oncolytics, added, "In this trial, we aim to demonstrate that the great potential shown by pelareorep in our lead breast cancer program can be extended to other advanced malignancies for which new treatments are needed. Pelareorep's potential in GI cancers is supported by the encouraging early clinical data we previously reported in pancreatic and colorectal cancer, which showed 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). We hope the GOLET study, in addition to providing positive safety and efficacy data, will also support our previously identified predictive blood-based biomarkers CEACAM6 and T cell clonality. This will allow us to select the most appropriate patients for future registration studies, thereby increasing their likelihood of success."

The GOLET study will make use of a new master clinical supply agreement between Oncolytics and Roche. Per the agreement, Roche will supply atezolizumab for use in Oncolytics' clinical development plan.

Andrew de Guttadauro, President of Oncolytics Biotech U.S. and Global Head of Business Development, said, "The GOLET study represents an exciting opportunity to further expand the commercial opportunity of pelareorep beyond our primary focus of breast cancer. We are especially grateful for Roche's support of this study, which we view as an encouraging sign for pelareorep, the study design, and our strategy to develop pelareorep-based therapies in collaboration with industry leaders. We are hopeful that the continued execution of this strategy could result in the rapid development and approval of pelareorep-based therapies for use in metastatic breast cancer and other indications."

About GOLET

The GOLET (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 GI tumors. The study will be conducted at 25 centers in Germany. The primary endpoint of the study is safety, with overall response rate and blood-based biomarkers (T cell clonality and CEACAM6) as exploratory endpoints. Approximately 55 patients are planned for enrollment across four separate 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 2nd and 3rd line metastatic colorectal cancer patients that are diagnosed as MSI high (microsatellite instability) (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 Tecentriq®

Tecentriq® (atezolizumab) is a registered trademark of Genentech, a member of the Roche Group.

About Pelareorep

Pelareorep is a non-pathogenic, proprietary isolate of the unmodified reovirus: a first-in-class intravenously delivered immuno-oncolytic virus for the treatment of solid tumors and hematological malignancies. The compound induces selective tumor lysis and promotes an inflamed tumor phenotype through innate and adaptive immune responses to treat a variety of cancers and has been demonstrated to be able to escape neutralizing antibodies found in patients.

About AIO

AIO-Studien-gGmbH (AIO) emerged from the study center of the [internal oncology working group](#) within the German Cancer Society. 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 Oncotherapy Biotech Inc.

Oncolytics is a biotechnology company developing pelareorep, an intravenously delivered immuno-oncolytic virus. The compound induces selective tumor lysis 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 additional studies in combination with checkpoint inhibitors and targeted therapies in solid and hematological malignancies, as it prepares for a phase 3 registration study in metastatic breast cancer. For further information, please visit: www.oncotherapybiotech.com.

References:

1. Arnold M, Abnet CC, Neale RE, Vignat J, Giovannucci EI, McGlynn KA, Bray F. Global Burden of 5 Major Types of Gastrointestinal Cancer. *Gastroenterology*. 2020 Apr 2:S0016-5085(20)30452-2. doi: 10.1053/j.gastro.2020.02.068.
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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, including the Company's belief as to the potential and mode of action of pelareorep as a cancer therapeutic; the design, aims and timing of our GOLET gastrointestinal cancer study; the potential for the GOLET study to expand the commercial opportunity of pelareorep beyond the Company's primary focus of breast cancer; the potential for our planned strategic approach to result in the rapid development and approval of pelareorep-based therapies for use in metastatic breast cancer and other indications; and other statements related to anticipated developments in the Company's business and technologies involve known and unknown risks and uncertainties, which could cause the Company's 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, the Company's 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 the Company 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 the Company's 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 to update these forward-looking statements, except as required by applicable laws.

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