

Oncolytics Biotech® Collaborates with SOLTI to Conduct a Window of Opportunity Study in Breast Cancer with Pelareorep

CALGARY, Alberta and SAN DIEGO, Calif., Sept. 10, 2018 (GLOBE NEWSWIRE) -- Oncolytics Biotech® Inc. (NASDAQ: ONCY) (TSX: ONC), currently developing REOLYSIN® (pelareorep), an intravenously delivered immuno-oncolytic virus turning cold tumors hot, today announced a clinical collaboration with SOLTI, an academic research group dedicated to clinical and translational research in breast cancer. This clinical collaboration, being sponsored by Oncolytics and facilitated by SOLTI, is a window of opportunity study (WOO) in the neoadjuvant setting for breast cancer. Patients will receive the appropriate standard of care for their cancer subtype plus pelareorep with or without the anti-PD-L1 cancer immunotherapy atezolizumab (Tecentriq®). Patients are biopsied on day one, followed immediately by treatment and a final biopsy after three weeks, on the day of their mastectomy. Data generated from this study is intended to confirm that the virus is acting as a novel immunotherapy and to provide comprehensive biomarker data by breast cancer sub-type, to support Oncolytics' phase 3 study in metastatic breast cancer and is expected in mid 2019.

"We are thrilled to enter into this collaboration with SOLTI and sponsor this window of opportunity study. We expect that this study will provide additional biomarker and immunological data to support our planned phase three study in metastatic breast cancer," said Matt Coffey, President and CEO of Oncolytics Biotech. "This data should confirm the findings of our phase two study and generate a robust biomarker plan designed to potentially enhance our phase three program. Importantly, it will also generate additional data demonstrating how the promotion of a virally induced inflamed phenotype should synergise with checkpoint inhibitors targeting PD-L1 like atezolizumab."

The study, facilitated by SOLTI, will be coordinated by Dr. Aleix Prat, Head of Medical Oncology at the Hospital Clínic of Barcelona, Associate Professor of the University of Barcelona and the Head of the Translational Genomics and Targeted Therapeutics in Solid Tumors Group at August Pi i Sunyer Biomedical Research Institute (IDIBAPS) and member of Oncolytics' Scientific Advisory Board. SOLTI has a network of more than 300 professionals, mostly medical oncologists, in over 80 hospitals in Spain, Portugal, France and Italy. Final study design and other details will be announced upon enrollment of the first patient, expected around the end of 2018 or very early 2019.

"It has been demonstrated that when reovirus infects a tumor, it promotes the release of immuno-stimulatory signals. This in turn results in the upregulation of PD-L1 on tumor cells and the recruitment of inflammatory immune cells like NK-cells and cytotoxic T-cells to the tumor, which are required prerequisites for checkpoint inhibitors to function effectively. In short, it turns cold tumors hot," said Dr. Prat. "We believe pelareorep can demonstrate the necessary inflamed tumor phenotype to prime tumors for PD-L1 blockade, which could potentially represent a promising form of cancer immunotherapy combination with atezolizumab. Results from this study will seek to establish the virus as an important immuno-oncology agent in breast cancer, which could ultimately support the expansion of pelareorep beyond metastatic breast cancer into first-line therapy."

About Breast Cancer

Breast cancer is the most common cancer in women worldwide, with nearly 1.7 million new cases diagnosed in 2012, representing about 25 per cent of all cancers in women. Incidence rates vary widely across the world, from 27 per 100,000 in Middle Africa and Eastern Asia to 92 per 100,000 in Northern America. It is the fifth most common cause of death from cancer in women, with an estimated 522,000 deaths (6.4 per cent of the total).

Breast cancer starts when cells in the breast begin to grow out of control. These cells usually form a tumor that can often be seen on an x-ray or felt as a lump. The tumor is malignant (cancer) if the cells can grow into (invade) surrounding tissues or spread (metastasize) to distant areas of the body.

Genomic research has led to a better understanding of how genes and proteins classify breast cancer as hormone receptor positive, human epidermal growth factor receptor 2 negative (HR+/HER2-), hormone receptor positive, human epidermal growth factor receptor 2 positive (HR+/HER2+), hormone receptor negative, human epidermal growth factor receptor 2 positive (HR-/HER2+) or triple negative breast cancer (TNBC).

About Pelareorep

Pelareorep, is a non-pathogenic, proprietary isolate of the unmodified reovirus: a first-in-class intravenously delivered immuno-oncolytic virus being evaluated 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.

About SOLTI

SOLTI is a non-profit association with more than 20 years of experience in conducting innovative clinical and translational research to address unmet medical needs in breast cancer that answer questions of major scientific interest and relevance in the field of oncology. SOLTI has a network of more than 300 professionals, mostly medical oncologists, distributed in over 80 hospitals in Spain, Portugal, France and Italy. For more information, please visit: www.gruposolti.org.

About Oncolytics 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. Oncolytics' clinical development program emphasizes three pillars: chemotherapy combinations to trigger selective tumor lysis and immuno-therapy and immune modulator (IMiD) combinations to produce innate and adaptive immune responses. Oncolytics is currently conducting and planning additional studies in combination with checkpoint inhibitors and targeted and IMiD 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.oncolyticsbiotech.com.

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

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 REOLYSIN, also known as pelareorep, as a cancer therapeutic; 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. 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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