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# **Oncolytics Biotech (R) Announces Study to Investigate Combination of Pelareorep and Avelumab in Metastatic Breast Cancer in Collaboration with Merck KGaA, Darmstadt, Germany, and Pfizer**

***Phase 2 BRACELET-1 study to evaluate Oncolytics' systemically delivered oncolytic virus, pelareorep, in combination with paclitaxel and anti-PD-L1 antibody avelumab***

**SAN DIEGO, CA and CALGARY, AB / ACCESSWIRE / June 5, 2019/** Oncolytics Biotech<sup>®</sup> Inc. (NASDAQ: ONCY) (TSX: ONC), currently developing pelareorep, an intravenously delivered immuno-oncolytic virus, today announced that the company has entered into an agreement with Merck KGaA, Darmstadt, Germany, a leading science and technology company, which operates in the US and Canada as EMD Serono, and Pfizer Inc. (NYSE: PFE). The agreement is to co-develop pelareorep in combination with paclitaxel and avelumab\*, a human anti-PD-L1 antibody, for the treatment of hormone-receptor positive, human epidermal growth factor 2-negative (HR+ / HER2-) metastatic breast cancer. Oncolytics and Pfizer will share costs associated with the phase 2 clinical trial.

"Our co-development agreement with Merck KGaA, Darmstadt, Germany and Pfizer reflects a growing interest in the potential synergistic effect of oncolytic viruses and immune checkpoint inhibitors and provides yet another point of validation for our technology," said Dr. Matt Coffey, President and Chief Executive Officer of Oncolytics Biotech. "We believe pelareorep has broad applicability to boost the effectiveness of a range of checkpoint inhibitors across multiple cancer indications. We are excited to work with Merck KGaA, Darmstadt, Germany, and Pfizer and look forward to quickly developing the program to evaluate the efficacy and safety in metastatic breast cancer and potentially examining pelareorep in combination with other immunotherapies."

"We look forward to working with Oncolytics to assess the potential synergies of avelumab with their oncolytic virus platform to treat metastatic breast cancer." said Chris Boshoff, M.D., Ph.D., Senior Vice President and Chief Development Officer, Oncology, Pfizer.

"Through our collaboration with Oncolytics, we continue to advance our strategy to develop innovative immunotherapy combinations tackling the most challenging cancers," said Kevin Chin, Vice President, Global Clinical Development, Immuno-Oncology at the biopharma business of Merck KGaA, Darmstadt, Germany, which in the US and Canada operates as EMD Serono.

The study known as BRACELET-1 (**BR**east **cAn**CEr with the Oncolytic Reovirus

PeLareorEp in CombinaTion with anti-PD-L1 and Paclitaxel) is an open label study that will enroll 45 patients into three cohorts with 15 patients per cohort: paclitaxel alone, paclitaxel in combination with pelareorep and paclitaxel in combination with both pelareorep and avelumab. The study will examine the expression of immune-related biomarkers to identify changes in T cell clonality between pre-treatment and on-therapy biopsies to confirm our previously identified biomarker and is designed to assess efficacy in terms of overall response rate at week 16 per RECIST 1.1 and iRECIST. The safety of the combination will also be evaluated. During the period of the study and for 90 days after a pre-determined interim analysis, Oncolytics may exclusively develop pelareorep in HR+ / HER2- metastatic breast cancer with Merck KGaA, Darmstadt, Germany, and Pfizer.

\*Avelumab is under clinical investigation for treatment of hormone receptor-positive, human epidermal growth factor 2-negative (HR+ / HER2-) metastatic breast cancer and has not been demonstrated to be safe and effective for this use. There is no guarantee that avelumab will be approved for HR+ / HER2- metastatic breast cancer by any health authority worldwide.

### **About avelumab**

Avelumab is a human anti-programmed death ligand-1 (PD-L1) antibody. Avelumab has been shown in preclinical models to engage both the adaptive and innate immune functions. By blocking the interaction of PD-L1 with PD-1 receptors, avelumab has been shown to release the suppression of the T cell-mediated antitumor immune response in preclinical models.<sup>3-5</sup> Avelumab has also been shown to induce NK cell-mediated direct tumor cell lysis via antibody-dependent cell-mediated cytotoxicity (ADCC) *in vitro*.<sup>5-7</sup> In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

### **Avelumab Approved Indications**

Avelumab (BAVENCIO<sup>®</sup>) in combination with axitinib is indicated in the US for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO<sup>®</sup>) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Avelumab is currently approved for patients with MCC in more than 45 countries globally, with the majority of these approvals in a broad indication that is not limited to a specific line of treatment.

### **Avelumab Important Safety Information from the US FDA-Approved Label**

The warnings and precautions for avelumab (BAVENCIO<sup>®</sup>) include immune-mediated

adverse reactions (such as pneumonitis and hepatitis [including fatal cases], colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions [which can be severe and have included fatal cases]), infusion-related reactions, major adverse cardiovascular events (MACE), and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with BAVENCIO® include fatigue, musculoskeletal pain, diarrhea, nausea, infusion-related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash. Additional common adverse reactions reported in patients receiving BAVENCIO® in combination with axitinib include hypertension, mucositis, palmar-plantar erythrodysesthesia, dysphonia, hypothyroidism, hepatotoxicity, cough, dyspnea, abdominal pain, and headache. Clinical chemistry and hematology laboratory value abnormalities have been reported including but not limited to grade 3-4 lymphopenia, anemia, elevated cholesterol and liver enzymes.

For full Prescribing Information and Medication Guide for BAVENCIO®, please see [www.BAVENCIO.com](http://www.BAVENCIO.com).

### **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 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. 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.oncolyticsbiotech.com](http://www.oncolyticsbiotech.com).

*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 plans to co-develop pelareorep in combination with paclitaxel and avelumab and the anticipated sharing of costs associated therewith; the Company's proposed BRACELET-1 study and the anticipated design, enrollment and timing thereof; the Company's other development plans for pelareorep; the Company's belief as to the potential and mode of action of 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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