June 6, 2022

Intensity Therapeutics, The Ottawa Hospital and The Ontario Institute for Cancer Research Report INT230-6 Demonstrates Tumor Necrosis and Immune Activation in Early Stage Breast Cancers

Significant Necrosis Demonstrated in Invasive Ductal and Lobular Cancers, Which are Normally Resistant to Chemotherapy.

One or Two Doses of INT230-6 Resulted in 85% to 95% Necrosis of 4 cm Invasive Tumors

Within the Tumor Microenvironment, There was a Relative Increase in Abundance of CD8 Memory T, CD4 Naïve and B Cells Post-Treatment

No Surgery was Delayed or Cancelled, and No Surgical Procedure Altered

WESTPORT, Conn. and OTTAWA, ON and TORONTO, June 6, 2022 /PRNewswire/ -- The Ottawa Hospital, The Ontario Institute of Cancer Research ("OICR") and **Intensity Therapeutics, Inc.** ("Intensity"), a clinical-stage biotechnology company focused on the discovery and development of proprietary, novel immune-based intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, today presented data from the INVINCIBLE study, a randomized, phase 2 presurgical Window-Of-Opportunity trial for Intratumoral INT230-6 comprising SHAO (dispersion enhancer), VINblastine (VIN) and Cisplatin (CIS) that is evaluating clinical and Biological Effects in patients with early-stage operable breast cancer. The study, presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago and virtually from June 3-7, 2022, reported data demonstrating efficacy and tolerability of INT230-6.

Abstract Title: *Intratumoral (IT) INT230-6 can cause tumor necrosis In Vivo: Preliminary results of a phase II randomized presurgical window-of-opportunity study in early breast cancers (the **INVINCIBLE** study).*
First Author: Angel Arnaout, MD, FACS
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Copies of the presentation materials will also be available on the Intensity Therapeutics website on the publications and posters page, following completion of the live presentation.

"For a breast cancer patient, the typical waiting period of 2-6 weeks from diagnosis to surgery is a very anxious time. Surgeons and patients feel helpless, as there are currently no therapeutic options for the patient during this time," said Angel Arnaout, M.D., Scientist and Surgical Oncologist at the Ottawa Hospital, and Professor of Surgery at the University of Ottawa. "The active drug agents comprising INT230-6 remain in the tumor following injection and can cause tumor cell death and high levels of necrosis in multiple breast cancer subtypes including triple negative breast cancer, as demonstrated by Part 1 of this study. Interestingly, we also saw immune activation with a relative increase in the abundance of CD4 T naïve, B and NK cells, post treatment, and within the tumor microenvironment, a relative increase in abundance of CD8 memory T, CD4 naïve and B cells, post treatment, when comparing drug treated with control samples. The ability to use just one or two doses of this agent to elicit a rapid and marked cytotoxic and immune induction response within the tumor during the surgical waiting period, all without an increase in postoperative complications, is very novel and highly attractive to patients. We are excited about how this may shift the paradigm on how we treat cancer patients awaiting surgery, in general. We look forward to future studies to demonstrate how this intra-tumoral agent can have systemic benefit and long term impact in patients with breast cancer."

"INT230-6 is our novel, proprietary, locally-delivered, tumor dispersive anti-cancer product that has shown favorable clinical results as monotherapy in a basket study of patients with advanced, relapsed and refractory disease," said Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "These first results reported from the INVINCIBLE breast cancer study provide evidence and support for the potential of our drug in treating local disease prior to surgery. The data from Part I of the INVINCIBLE study show that INT230-6 is well tolerated and, as we see in metastatic disease, elicits both rapid direct tumor killing and immune activating effects. We anticipate completing enrollment of Part II this summer and reporting the full patient study results at a future oncology conference."

About the INVINCIBLE Study

The INVINCIBLE study is a phase II, randomized, open label, multi-center study, expected to enroll up to 90 women with newly diagnosed operable early-stage intermediate or high-grade T1-T2 invasive breast cancers who are randomly allocated (2:1) prior to resection to IT injections of INT230-6, no treatment or saline sham injection. The study has two parts. Part I (N=29), now complete, randomized patients 2:1 to either 1-3 doses of INT230-6 injected weekly or no treatment, 2 to 5 weeks prior to surgery (lumpectomy or mastectomy). The purpose of this portion of the trial was to evaluate safety, feasibility, and optimal drug dosing. Part II is a double-blind, randomized arm of up to 60 patients, where patients will be randomized 2:1 to receive one or two IT doses of INT230-6 vs. saline injection. The objective of using saline will be to rule out the potential confounding effect of hydrostatic pressure on tumor necrosis. The results of Part II will further evaluate the potential cytotoxic, immunomodulatory and other biologic effects of INT230-6 and its role as a potential cancer therapy in breast cancer patients awaiting surgery. The INVINCIBLE Study is being conducted under a Health Canada (HC) approved Clinical Trial Application (CTA), under the direction and supervision of Principal Investigator, Dr. Angel Arnaout. OHRI will conduct subject enrollment and treatment, and evaluate clinical responses. OICR will analyze subject immune responses and conduct biomarker analyses.

About Potential INT230-6 Approval Pathways in the Presurgical Setting
The U.S Food and Drug Administration (FDA) instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint. Pathological complete response (pCR) is an accepted FDA accelerated approval criterion for approval in high risk breast cancer, such as TNBC subtype. pCR is defined as the absence of residual invasive and in situ cancer after evaluation of the complete resected breast specimen and lymph nodes following completion of neoadjuvant systemic therapy.

Data from the INVINCIBLE study will provide an understanding of the effect of INT230-6 on cancer cell proliferation and tumor necrosis. If INT230-6 causes increased tumor necrosis with good safety, then the addition of INT230-6 to the existing or a modified neoadjuvant (presurgical) systemic standard-of-care treatment regimen may increase pCR rates in TNBC. In November of 2020, Intensity Therapeutics met with FDA and discussed the potential use of INT230-6 in the presurgical neoadjuvant breast cancer setting in an accelerated approval program.

About INT230-6
INT230-6, Intensity's lead proprietary investigational product candidate, is designed for direct intratumoral injection. INT230-6 was discovered using Intensity's proprietary DfuseRx℠ technology platform. The drug is composed of two proven, potent anti-cancer agents, cisplatin and vinblastine, and a penetration enhancer molecule that helps disperse potent cytotoxic drugs throughout tumors for diffusion into cancer cells. These agents remain in the tumor, resulting in a favorable safety profile and the induction of an anti-cancer systemic immune response resulting in shrinkage of uninjected tumors.

About The Ottawa Hospital
The Ottawa Hospital is one of Canada's top learning and research hospitals, where excellent care is inspired by research and driven by compassion. As the third-largest employer in Ottawa, our support staff, researchers, nurses, physicians, and volunteers never stop seeking solutions to the most complex health-care challenges. Our multi-campus hospital, affiliated with the University of Ottawa, attracts some of the most influential scientific minds from around the world. Backed by generous support from the community, we are committed to providing the world-class, compassionate care we would want for our loved ones. www.ottawahospital.on.ca

About the Ontario Institute for Cancer Research
OICR is a collaborative, not-for-profit research institute funded by the Government of Ontario. We conduct and enable high-impact translational cancer research to accelerate the development of discoveries for patients around the world while maximizing the economic benefit of this research for the people of Ontario. For more information visit https://oicr.on.ca/

About Intensity Therapeutics' Clinical Studies
INT230-6 is currently being evaluated in several phase 2 cohorts (NCT03058289) in patients with various advanced solid tumors as part of Study IT-01. In 2019, the Company signed a clinical collaboration agreement with Merck Sharpe & Dohme (Merck) to evaluate the combination of INT230-6, Intensity's lead product candidate, and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced pancreatic, colon, squamous cell and bile duct malignancies. In 2020, the

Company executed a clinical collaboration agreement with Bristol-Myers Squibb to evaluate the combination INT230-6, with Bristol-Myers Squibb's anti-CTLA-4 antibody, Yervoy® (ipilimumab), in patients with advanced liver, breast and sarcoma cancers. Intensity is managing the individual combination arms separately with each respective partner via a joint development committee. In 2021, the Company executed agreements with the Ottawa Hospital Research Institute (OHRI) and the Ontario Institute of Cancer Research (OICR) to study INT230-6 in a randomized controlled neoadjuvant phase 2 study in women with early stage breast cancer (the INVINCIBLE study) (NCT04781725).

About Intensity Therapeutics
Intensity Therapeutics, Inc. is a clinical-stage biotechnology company pioneering a new immune-based approach to treat solid tumor cancers. Intensity leverages its DfuseRx℠ technology platform to create new, proprietary drug formulations that, following direct injection, rapidly disperse throughout a tumor and diffuse therapeutic agents into cancer cells. Intensity's product candidates have the potential to induce an adaptive immune response that not only attacks the injected tumor, but also non-injected tumors. In addition to its clinical collaborations, the Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch in 2014. For more information, please visit www.intensitytherapeutics.com and follow the Company on Twitter @IntensityInc.

Forward-Looking Statements
This press release contains forward-looking statements regarding Intensity Therapeutics' plans, future operations and objectives. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual performance or achievements to be materially different from those currently anticipated. These forward-looking statements include, among other things, statements about the initiation and timing of future clinical trials.

Contact Information

Investor Relations Contact:
Rx Communications Group
Michael Miller
917-633-6086
mmiller@rxir.com

US Media Contact:
KOGS Communication
Edna Kaplan
781-639-1910
kaplan@kogspr.com

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