November 10, 2022

Intensity Therapeutics, The Ottawa Hospital and 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.

Significant Necrosis from a Single Injection of up to 100% of a Tumor was Observed During the Trial

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

Results to be Presented at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting

WESTPORT, Conn. and OTTAWA, ON and TORONTO, Nov. 10, 2022 /PRNewswire/ -- **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, along with The Ottawa Hospital and Ontario Institute of Cancer Research ("OICR"), will present updated data from the INVINCIBLE study, a randomized, phase 2 presurgical window of opportunity trial for Intensity's 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, to be presented today at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting being held in Boston and virtually from November 8-12, 2022, will report data demonstrating efficacy and tolerability of INT230-6.

Abstract Number: 545
Title: *A Phase II Randomized Window of Opportunity Trial Evaluating Cytotoxic and Immunomodulatory effects of Intratumoral INT230-6 (Cisplatin, Vinblastine) in Early Stage Breast Cancer: the INVINCIBLE Trial*
First Author: Angel Arnaout, M.D., FACS
Session Date and Time: Thursday, November 10, 2022, 9:00 am - 9:00 pm EST
Location: Hall C; In-Person & On Demand

Copies of the presentation materials will be available on the Intensity Therapeutics website on the publications and posters page.

"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 and Co-lead of OICR's Window-of-Opportunity Network. "INT230-6 remains 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 intratumoral agent can have systemic benefit and long-term impact in patients with breast cancer."

"INT230-6's ability to rapidly cause high levels of tumor necrosis combined with immune activation in early stage breast cancer patients with only low grade adverse events is unprecedented and quite exciting," said Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "The results from the INVINCIBLE study, coupled with our data in metastatic patients, provide strong evidence and support for the potential of our drug in treating cancer patients from before surgery to late stage disease. We look forward to the full data set from the INVINCIBLE study and further development of our pioneering new medicine."

About the INVINCIBLE Study
The INVINCIBLE study (NCT 04781725), a phase 2, randomized, open label study, has enrolled 91 women with newly diagnosed, operable early-stage intermediate or high-grade T1-T2 invasive breast cancers 2 to 5 weeks prior to surgery (lumpectomy or mastectomy). Dose was set by the diameter of the tumor. Subjects were randomly allocated (2:1) prior to resection to 1 to 3 IT injections of INT230-6 versus no treatment (part 1 n=29) or saline sham injection (part 2 n=58). Part 1 evaluated safety, feasibility, and dose amounts. Part 2 was a double-blind, randomized arm. The objective of using saline will be to rule out the potential confounding effect of hydrostatic pressure on tumor necrosis. The results of Part 2 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. The Ottawa Hospital Research Institute conducted subject enrollment and treatment and will evaluate clinical responses. OICR will analyze subject immune responses and conduct biomarker analyses such as Ki67 and T-cell repertoire.

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 triple negative breast cancer (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 (SHAO) 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. In addition to local disease control, direct killing of the tumor by INT230-6 releases a bolus of neoantigens specific to the patient's malignancy, leading to engagement of the immune system and systemic anti-tumor effects. Importantly, these effects are mediated without the immunosuppression of concomitant systemic chemotherapy.

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 patients with various advanced refractory solid tumor cancers as part of Study IT-01 (NCT 03058289). 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 a variety of cancers. 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 a variety of 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) (NCT 04781725). Enrollment is both studies is now complete.

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 cause tumor necrosis and induce an adaptive immune response that not only attacks the injected tumor, but also non-injected tumors. In addition to partnerships with Merck and Bristol-Myers Squibb, 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
Certain statements in this press release may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These statements include, but are not limited to, statements relating to the expected trading commencement and closing dates. We have based these forward-looking statements on our current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements we make. These risks and uncertainties, many of which are beyond our control, include: the risk that the initial public offering of common stock may not close, as well as other risks described in the section entitled "Risk Factors" in the prospectus, which can be obtained on the SEC website at www.sec.gov. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management's current estimates, projections, expectations and beliefs. The company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

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