December 10, 2021

Intensity Therapeutics Reports Promising Early Efficacy Results Using INT230-6 as a Monotherapy or in Combination with Pembrolizumab in Metastatic Breast Cancer at the 2021 San Antonio Breast Cancer Symposium®

In a Highly Refractory Population the Disease Control Rate (DCR), at the First Radiologic Assessment, was 57%

Median Overall Survival was 12 months

Abscopal Effects Seen in 1 of 4 Monotherapy Subjects

WESTPORT, Conn., Dec. 10, 2021 /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, today reported safety, pharmacokinetic, biomarker and efficacy data using INT230-6, with and without pembrolizumab, in heavily pretreated refractory breast cancer patients as part of the Company's phase 1/2 study, IT-01. The presentation was made at the San Antonio Breast Cancer Symposium® (SABCS), being held virtually and in-person at the Henry B. Gonzales Convention Center in San Antonio, Texas.

The seven heavily pre-treated breast cancer subjects were enrolled in the study after having progressed on a median of six (range 2 to 10) prior therapies. The INT230-6 monotherapy subjects (n=4) were more heavily pre-treated with a median of eight prior therapies vs. three prior therapies for pembrolizumab combination subjects (n=3). The disease control rate (DCR), defined as the percent of breast cancer subjects with a complete response, partial response, or stable disease at the first radiologic assessment, was 57%. Study authors reported a median overall survival (mOS) of 12 months (CI:7.2, NR), which compares favorably to results seen in phase 1 studies of subjects with highly refractory or triple negative breast cancer. Abscopal effects were seen in a non-injected visceral lesion in 1 of 4 INT230-6 monotherapy subjects. A number of patients came off study after completion of INT230-6 dosing without disease progression. One subject continued receiving INT230-6 injections despite a new lesion.

Peak plasma concentrations of the agent vinblastine were less than five percent (5%) of that predicted, based on historical IV kinetics, indicating that 95% of the drug remains in the

tumor. Treatment related adverse events (TRAEs) were favorable with or without pembrolizumab. Only one subject experienced a grade 3 TRAE (monotherapy group) and there were no grade 4 or grade 5 TRAEs. Tissue analysis of matched paired (pre- and 28 days post-dose) biopsies in injected tumors from subjects receiving their first INT230-6 treatment cycle (two doses, n=3) had an average reduction in viable cancer cells of sixty-nine percent (69%). Immunohistochemistry results showed influx of CD4 and CD8 T-cells into the tumor microenvironment.

"Preliminary data suggests that INT230-6 demonstrates direct tumor killing in metastatic breast cancer subjects including those with triple negative breast cancer (TNBC) and may elicit an anti-cancer immune response within the injected tumor with or without pembrolizumab," stated poster presenter and study investigator, Philippe Bedard, M.D., Clinician Investigator, Princess Margaret Cancer Centre in Toronto Canada. "Additionally, INT230-6 treatment related adverse events are mostly low grade and the drug is well-tolerated either as a monotherapy or in combination with anti-PD-1 therapy, pembrolizumab. These results provide evidence to continue studying this novel therapeutic drug approach in breast cancer."

"The data presented at the San Antonio Breast Cancer Symposium using INT230-6 alone or in combination with pembrolizumab were generated from refractory breast cancer patients treated in the dose escalation portion of our phase 1 clinical study, IT-01, and these results are encouraging. We have also learned a great deal about our drug in breast cancer from our trial in metastatic patients and our phase 2 randomized INVINCIBLE study, which is testing INT230-6 in breast cancer patients in a presurgical setting," said Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "We are excited about conducting additional clinical studies using INT230-6 in metastatic breast cancer as part of INT230-6's Fast Track designation as well as in presurgical patients, as there remains an unmet medical need for safer more effective treatments in both settings."

Presentation Title: *Safety and efficacy of INT230-6, a potential first-in-class intratumoral therapy, in monotherapy and in combination with pembrolizumab: Results from the IT-01 study [KEYNOTE-A10] in subjects with locally advanced, unresectable and metastatic breast cancer*
Abstract: 541
Poster Number: P-5-16-13
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Session: Treatment: Therapeutic Strategies - New Drugs and Treatment Strategies
Date: Friday, December 10, 2021

Time: 7:00AM – 8:30AM Central Standard Time

The presentation will be accessible on the "Publications, Papers and Posters" section of Intensity's website at: https://intensitytherapeutics.com/news/publications-papers-and-posters on December 10, 2021.

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 an amphiphilic penetration enhancer molecule that helps disperse the drugs throughout tumors for diffusion into cancer cells. In addition to local disease control, direct killing of the tumor by INT230-6 releases 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.

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 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 Company to evaluate the combination of INT230-6 with Bristol-Myers Squibb's anti-CTLA-4 antibody, Yervoy® (ipilimumab), in patients with advanced liver, breast and sarcoma cancers. In 2021, the Company executed agreements with the Ottawa Hospital Research Institute and the Ontario Institute of Cancer Research to study INT230-6 in a randomized controlled neoadjuvant phase 2 study in women with early stage breast cancer (the INVINCIBLE study) (NCT04781725).

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

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 systemic immune response that not only attacks the injected tumor, but also non-injected tumors. The Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch in 2014 and has partnerships with Merck and Bristol-Myers Squibb. For more information, please visit www.intensitytherapeutics.com.

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.

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