November 7, 2019

# Data From Intensity Therapeutics' Phase 1/2 Study of INT230-6 Highlight Prolonged Disease Control, Abscopal Effects and Immune Response Activity in Patients With Advanced Solid Tumors

- Data to be shared during oral podium presentation at SITC 2019
- Durable clinical benefit seen in multiple patients
- Abscopal responses in non-injected tumors and increases in circulating CD4 and CD8 T-cells indicate immune activation

WESTPORT, Conn.--(BUSINESS WIRE)-- Intensity Therapeutics, Inc., a clinical-stage biotechnology company developing proprietary intratumoral immunotherapy products to kill tumors and increase immune system recognition of solid cancers, today announced new preliminary data from the ongoing Phase 1/2 clinical study of INT230-6, the Company's lead product candidate. These data will be presented on Saturday, November 9, in an oral podium presentation at the Society for Immunotherapy of Cancer's (SITC) 34th Annual Meeting, being held in National Harbor, MD.

"The data being presented at SITC advance our understanding of this new treatment, and identify a patient population that seems to derive the most benefit," said presenter and study investigator Jacob Thomas, MD, Assistant Professor of Clinical Medicine, Keck School of Medicine of the University of Southern California. "Our study included a highly refractory patient population, nonetheless several patients have had long term benefit. We observed a disease control rate of 39 percent in evaluable patients, with several patients showing disease control for over one year. In patients that had over 50 percent of total tumor burden injected, seven out of eight patients have shown disease control including all four patients enrolled with metastatic breast cancer. The treatment is well tolerated, and no patients had to discontinue therapy due to treatment-related toxicity. Additional benefits included tumor shrinkage and no further tumor growth or new tumors."

"We are excited that the data thus far reproduce the animal findings that intratumoral injection of INT230-6 stays in the tumor and the patients tolerate the procedure and drugs well. It also demonstrates cancer cell death in treated and in uninjected tumors with systemic immune activation," said Ian B. Walters, MD, Chief Medical Officer of Intensity Therapeutics. "Having the ability to safely reduce tumor cell burden and prime an immune response is an important advance in our ability to manage refractory cancers, we look forward to evaluating the combination with Keytruda and other immune agents."

The oral podium presentation includes data on 45 heavily pretreated patients with 17 different types of advanced or metastatic solid tumors who have failed a median of three

prior therapies and are not candidates for approved, available therapies.

A pharmacokinetic (PK) analysis revealed limited exposure in the blood of INT230-6's active anticancer agents, cisplatin (CIS) and vinblastine (VIN), supporting that the majority of INT230-6 is retained in the tumor, with few systemic toxicities. The findings are consistent with the low incidence of systemic adverse events despite intratumoral doses of INT230-6 escalating up to 160 mL, which is twice the amount of VIN that would typically be contained in a standard intravenous (IV) dose.

Furthermore, the immune activation data observed were consistent with nonclinical data, as local delivery of INT230-6 into tumors induced an immune response with increases of CD4+ and CD8+ T-cells in the blood and in the tumor microenvironment without any immune-related adverse events. An abscopal response was demonstrated in seven patients who overall showed tumor shrinkage in 10 non-injected tumors.

**Oral Podium Presentation Information**

**Title:** Intratumoral INT230-6 injection into solid tumors kills tumors and induces immune cell infiltration leading to abscopal responses and prolonged disease control in multiple refractory cancer types
**Abstract Number:** O31
**Date/Time:** Saturday, November 9, 2019, 3:45-4:00 p.m. ET
**Session:** Concurrent Session 309: Single Agent Phase 1 Clinical Trials
**Location:** Prince George's Exhibition Hall C
**Presenter:** Jacob Thomas, MD, Assistant Professor of Clinical Medicine, University of Southern California

**About INT230-6**

INT230-6, Intensity's lead proprietary product candidate, is designed for direct intratumoral injection. INT230-6 was discovered using Intensity's proprietary DfuseRx℠ technology platform. The drug is comprised of two proven, potent anti-cancer agents, cisplatin and vinblastine, and a penetration enhancer molecule that helps disperse the drugs throughout tumors for diffusion into cancer cells. In preclinical studies, INT230-6 eradicated tumors by a combination of direct tumor killing, releasing tumor antigens and recruitment of immune cells to the tumor. Results generated by the National Cancer Institute (NCI) showed treatment with INT230-6 in *in vivo* models of severe cancer resulted in substantial improvement in overall survival compared to standard therapies. Further, INT230-6 provided complete responder animals with long-term, durable protection from multiple re-challenges of the initial cancer and resistance to other cancers. The NCI and Intensity collaborative research, published in July 2019, showed that there was also strong synergy when INT230-6 was combined with anti-PD-1 and anti-CTLA-4 antibodies. INT230-6 is being evaluated in a Phase 1/2 clinical study (NCT03058289) in patients with various advanced solid tumors. There have been no dose limiting adverse events observed in patients to date, even when dosing into deep tumors in the lung and liver. Several patients demonstrated tumor shrinkage, symptomatic improvement, and evidence of cancer cell death and immune cell activation on tumor biopsy.

**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. The Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch in 2014. The Company is also collaborating with Merck Sharpe & Dohme 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 solid malignancies. For more information, please visit www.intensitytherapeutics.com and follow us 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.*

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