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Intensity Therapeutics Highlights INT230-6 Data in Advanced Solid Tumors at Society for Immunotherapy of Cancer's (SITC) 33rd Annual Meeting

- Intratumoral injections of INT230-6 were well tolerated with no drug-related serious adverse events or dose-limiting toxicity in Phase 1/2 clinical study
- Preclinical research demonstrates drug dispersion benefit of DfuseRx^{SM} technology

WESTPORT, Conn., Nov. 08, 2018 (GLOBE NEWSWIRE) -- Intensity Therapeutics, Inc., a clinical-stage biotechnology company developing proprietary immune cell-activating cancer treatments, today announced additional data from a Phase 1/2 clinical study of INT230-6, the Company's novel lead product candidate designed for direct intratumoral injection, and preclinical research highlighting the Company's proprietary DfuseRx^{SM} technology will be presented in a poster (P622) at the Society for Immunotherapy of Cancer's (SITC) 33rd Annual Meeting in Washington, D.C.

INT230-6 is comprised of two proven, potent anti-cancer agents and a unique molecule that causes rapid drug dispersion throughout tumors and diffusion into cancer cells.

The presenting author and a study investigator, Anthony Olszanski, MD, Vice Chair of the Department of Hematology/Oncology and Director of the Phase 1 Developmental Therapeutics Program at Fox Chase Cancer Center, said, "We are pleased to share post-treatment imaging of a patient with heavily pretreated cutaneous squamous cell carcinoma who had two deep tumors in the upper arm. Following treatment with INT230-6, scans revealed increased tumor necrosis. In addition, a patient with a chordoma achieved excellent tumor reduction, with some non-injected lesions also decreasing in size, following treatment with INT230-6 as monotherapy, even when administered at low doses. These encouraging results, in addition to a very promising safety profile, support the continued evaluation of INT230-6 in patients with advanced solid tumors."

INT230-6 was discovered using Intensity's DfuseRx^{SM} technology platform. Preclinical research demonstrated the enhanced ability of INT230-6 to saturate murine pancreatic cancer tumors, compared to the drug alone.

"Our preclinical animal data of INT230-6 shows its ability to disperse and saturate a tumor with drug when administered at the proper dose-to-tumor volume ratio," said Lewis H. Bender, Founder and CEO of Intensity Therapeutics. "When dosing intratumorally, proper drug dispersion is critical in order to treat the entire tumor effectively, especially in regions away from the blood vessels that are hypoxic. Data also show that our highly efficient tumor-killing product, INT230-6, induces a strong adaptive immune response to attack untreated

lesions and metastases."

Ian B. Walters, MD, Chief Medical Officer of Intensity, added, "The latest data from Intensity's clinical study evaluating INT230-6 in patients with different types of solid tumors continues to indicate that INT230-6 can be safely injected, even into deep tumors. The vast majority of the active components of INT230-6 stay inside the tumor, and most reports are limited to mild to moderate local discomfort from the injection."

Intensity plans to add more North American clinical sites, as well as international sites, to the Phase 1/2 clinical study of INT230-6. The Company also plans to move into combination arms with an anti-PD-1 antibody and begin Phase 2 expansion cohorts in specific tumor types next year.

About INT230-6
INT230-6, Intensity's lead product candidate designed for direct intratumoral injection, is comprised of two proven, potent anti-cancer agents and a penetration enhancer molecule that helps disperse the drugs throughout tumors and diffuse into cancer cells. INT230-6 is being evaluated in a Phase 1/2 clinical study (NCT03058289) in patients with various advanced solid tumors. In preclinical studies, INT230-6 eradicated tumors by a combination of direct tumor kill and recruitment of dendritic cells to the tumor micro-environment that induced anti-cancer T-cell activation. 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-inoculations of the initial cancer and resistance to other cancers. In mouse models, INT230-6 has shown strong synergy with checkpoint blockage, including anti-PD-1 and anti-CTLA4 antibodies. INT230-6 was discovered from Intensity's DfuseRx^{SM} platform.

About the Phase 1/2 Clinical Study
INT230-6 is being evaluated in a Phase 1/2 clinical study in patients with different types of advanced solid tumor malignancies. The study's primary objective is to assess the safety and tolerability of multiple intratumoral doses of INT230-6. Secondary assessments are the measurement of injected and bystander tumor responses, and determination of the systemic pharmacokinetic profile of multiple doses of INT230-6's drug substances after single and then multiple intratumoral injections. Exploratory analysis will characterize patient outcome, as well as evaluate various tumor and anti-tumor immune response biomarkers that may correlate with response. The study includes several adaptive components that will allow for adjustments in patient groups, dosing schedule and dose volumes administered. Data will be used to assess the progression free and overall survival in patients receiving INT230-6. For more information, please visit www.clinicaltrials.gov (NCT03058289).

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^{SM} technology platform to create new 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 and unseen micro-metastases. INT230-6, Intensity's lead product candidate, is being evaluated in a Phase 1/2 clinical study

in patients with various advanced solid tumors. 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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