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Intensity Therapeutics Announces Preliminary Data from Clinical Study of INT230-6 in Advanced Solid Tumors

- **Intratumoral injections of INT230-6 were well tolerated with no drug-related serious adverse events or dose-limiting toxicity**
- **Increases in circulating CD8 and CD4 T-cells and evidence of abscopal responses in non-injected tumors observed**

WESTPORT, Conn., Oct. 22, 2018 (GLOBE NEWSWIRE) -- Intensity Therapeutics, Inc., a clinical-stage biotechnology company developing proprietary immune cell-activating cancer treatments, today announced preliminary data from a Phase 1/2 clinical study demonstrated that INT230-6, the Company's novel lead product candidate designed for direct intratumoral injection, was well tolerated in patients with advanced solid tumors. The data were presented in a poster session on Saturday at the European Society for Medical Oncology (ESMO) 2018 Congress in Munich, Germany.

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. In preclinical studies, INT230-6 demonstrated the ability to thoroughly saturate and kill injected tumors and induce an adaptive immune response that attacks non-injected tumors.

"We are pleased to share the first clinical data emerging from Intensity's study evaluating INT230-6 in patients with different types of solid tumors. This early data indicates that INT230-6 can be safely injected into several different types of superficial and deep tumors, and the vast majority of the active components stay inside the tumor," said Ian B. Walters, MD, Chief Medical Officer of Intensity.

The presenting author and a study investigator, Anthony El-Khoueiry, MD, Associate Professor of Clinical Medicine and phase I program director at the University of Southern California Norris Comprehensive Cancer Center, said, "We have treated 20 patients in the study thus far, and the intratumoral injections of INT230-6 have been well tolerated. Most patients experienced mild to moderate transient local pain and swelling. Even at low doses, we are seeing some anti-tumor effects in injected tumors, as well as some evidence of immune activation in the blood. There are also early signs of anti-tumor effects in distal untreated tumors."

Dr. Walters added, "The study will continue to enroll patients with difficult-to-treat tumors as we explore higher doses. We look forward to adding more North American sites, as well as new centers outside the U.S. and Canada. In addition, we plan to move into combination arms with an anti-PD-1 antibody and begin Phase 2 expansion cohorts 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.

Contacts

Investors:
Lewis Bender
Founder & CEO, Intensity Therapeutics

(914) 329-6571
lbender@intensitytherapeutics.com

Media:
Tony Plohoros
6 Degrees PR
(908) 591-2839
tplohoros@6degreespr.com

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