June 1, 2019

Intensity Therapeutics Presents Positive Preliminary Phase 1/2 Results for Intratumoral Injection of INT230-6 at ASCO 2019

- INT230-6 well tolerated at all doses given
- Durable clinical benefit seen in multiple patients
- Increases in circulating and intratumoral CD4 and CD8 T-cells along with abscopal responses in non-injected tumors indicate immune activation

WESTPORT, Conn.--(BUSINESS WIRE)-- Intensity Therapeutics, Inc., a clinical-stage biotechnology company pioneering a novel, immune-based approach to treat solid tumor cancers through direct injection of its proprietary therapeutic agents, today announced positive preliminary results from the company's ongoing Phase 1/2 clinical trial of its lead product candidate, INT230-6, in a poster at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

The poster highlights the results of 34 patients with 15 different types of advanced or metastatic solid tumors that have failed all or are not candidates for approved, available therapies.

INT230-6 was well tolerated in doses up to 120 mL, including intratumoral dosing into more than 100 tumors deep in the body. The 120 mL dose of INT230-6 contains amounts of the cytotoxic agents greater than a typical intravenous (IV) dose. Based on comparisons to historical IV data of the active agents comprising INT230-6, the observed pharmacokinetic profiles indicate that drug remains mostly in the tumor following INT230-6 dosing. While the trial is aimed at assessing safety, several patients have shown tumor shrinkage and prolonged disease control after completing INT230-6 treatment. The results show greater benefit in patients who have received higher doses, and who have had multiple tumors injected. Dose escalation is ongoing.

Additionally, the immune activation data observed was 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. Several patients have had shrinkage of non-injected tumors indicating an abscopal response.

"We are excited and encouraged by the positive preliminary results of our Phase 1/2 trial," said Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "It is our aim to improve cancer treatment, reduce the side effects associated with systemic therapies and improve patient outcomes using intratumorally dosed INT230-6."

“The patients in our trial have a tremendous need for a new therapy. They have failed a median of three prior treatments with a number of patients having progressed following seven or more drug therapies,” said Ian B. Walters, MD, Chief Medical Officer of Intensity Therapeutics. “Thus far, the data indicate that direct intratumoral injection of our product minimizes systemic side effects while promoting an augmented natural immune response that can fight a patient’s cancer for several months following completion of our treatment.”

Details of the poster presentation are as follows:

Title: Safety profile of INT230-6, a novel intratumoral (IT) formulation, during injections into a variety of refractory deep and superficial tumors with evidence of tumor regression and immune activation

Abstract Number: 2602

Date/Time: Saturday, June 1, 2019, 8-11 a.m. CDT

Poster Session: Developmental Immunotherapy and Tumor Immunobiology

Presenter: Anthony El-Khoueiry, MD, Associate Professor of Clinical Medicine and Director of the Phase I Drug Development Clinical Program, University of Southern California

About INT230-6

INT230-6, Intensity’s lead proprietary product candidate, is designed for direct intratumoral injection. The drug 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 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, 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. 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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