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Intensity Therapeutics, Inc. Reports Positive Safety Data from Ongoing IT-01 Phase 1/2 Trial

- *Study Steering Committee approves opening cohorts for dosing to deep tumors and more frequent treatment into superficial tumors*
- *First dosing to a patient's deep tumor achieved*
- *Necrosis of injected superficial tumors observed*

WESTPORT, Conn.--(BUSINESS WIRE)-- Intensity Therapeutics, Inc., a privately held biotechnology company developing proprietary cancer immune-based drug products for direct intratumoral injection, today announced completion of the first safety cohort (A) of the Company's Phase 1/2 international clinical study evaluating lead product, INT230-6. Following intratumoral drug injections into superficial lesions in six patients with either ovarian, thyroid, head and neck or skin cancers, there were no dose limiting toxicities. The investigators reported three drug-related, local, mild-to-moderate reversible adverse events, no drug-related series adverse events, no systemic adverse events and no procedure-related adverse events. These results were consistent with the observed low systemic exposure levels of the active agents comprising INT230-6.

Following the review of all patient data, the Study Steering Committee (SSC) decided to initiate treatment in patients with deep tumors (cohort B1) and to increase the frequency and dose for superficial tumors (cohort E). As a result, the study has now enrolled and dosed a sentinel patient's deep tumor, a bile duct carcinoma in the liver.

"The Study Steering Committee's decision to initiate INT230-6 injections into the deep tumor cohort and the treatment of our first such patient are important program milestones that demonstrate significant progress," said President and CEO, Lewis H. Bender. "We will now be able to test our drug in cancers with great unmet medical need such as pancreatic, liver, cholangiocarcinoma and even glioblastoma. These conditions do not typically respond to conventional therapies and long-term patient survival is quite poor."

"We are encouraged with the preliminary safety results of INT230-6 and are pleased by the observation of necrosis in the injected tumors even at low dose," said Chief Medical Officer Ian B. Walters, MD. "Our murine studies with INT230-6 have shown our drug's ability to stimulate a strong adaptive immune response in addition to the direct tumor killing effect. Those results also indicated a substantial benefit when our drug is given with an anti-PD-1 agent. Thus, as part of our clinical study, we have planned a cohort that combines our INT230-6 with checkpoint blockade compounds such as anti-PD-1 antibodies. Intensity Therapeutics is grateful to the volunteers participating in our study. We look forward to collecting more data on INT230-6 in different cancer types and to presenting our results at a scientific conference as soon as possible."

About INT230-6

INT230-6 is a novel, anti-cancer drug for direct intratumoral injection. The product contains potent anti-cancer agents that disperse throughout tumors and diffuse into cancer cells. INT230-6 was identified from Intensity's DfuseRx^{SM} platform and is being evaluated in a clinical trial; IT-01. In preclinical studies INT230-6 administration eradicated tumors by a combination of direct tumor kill coupled with 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.

About Study IT-01

IT-01 is entitled *A Phase 1/2 Safety Study of Intratumorally Administered INT230-6 in Adult Subjects with Advanced Refractory Cancers.* The trial aims to enroll approximately 60 patients with different types advanced solid tumor malignancies in a multicycle dosing regimen. The study will be conducted in multiple countries and includes a cohort combining INT230-6 with an anti-PD-1 antibody. Currently the study is recruiting in the U.S. and in Canada. The study's primary objective is to assess the safety and tolerability of multiple intratumoral doses of INT230-6. Secondary assessments are to understand preliminary efficacy of INT230-6 by measuring the injected and bystander tumor responses. The study will characterize 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 trial 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 subjects receiving INT230-6. Further information can be found at www.clinicaltrials.gov (NCT#03058289).

About Intensity Therapeutics, Inc.

Intensity Therapeutics, Inc. is a clinical-stage biotechnology company whose mission is to greatly extend the lives of patients with cancer. Intensity Therapeutics is pioneering a new immune-based approach to treat cancer. The Company uses its DfuseRx^{SM} platform technology to create new drug formulations that following direct injection rapidly disperse throughout a tumor and diffuse therapeutic agents into cancer cells. Drug products created using the technology are capable of attenuating (killing) a tumor in a manner that allows for the adaptive immune system to recognize the cancer and attack distal tumors and micrometastases. Further information can be found at 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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