Intensity Therapeutics, Inc. Successfully Administers INT230-6 to First Patient in a Phase 1/2 Trial

- Study being conducted under both an accepted IND from the U.S. Food and Drug Administration and a CTA from Health Canada

Westport, CT. – May 30, 2017 - Intensity Therapeutics, Inc., a privately held biotechnology company developing proprietary cancer immunotherapy products, today announced that the first patient successfully received treatment with the Company's lead product, INT230-6, as part of a Phase 1/2 international clinical study. Initiation of the study followed acceptance of an investigational new drug (IND) submission by the US Food and Drug Administration's Division of Oncology Products 1 (DOP1) and receipt from Health Canada of a No Objection Letter following submission of a clinical trial application (CTA). The clinical trial, IT-01 (NCT#03058289), entitled *A Phase 1/2 Safety Study of Intratumorally Administered INT230-6 in Adult Subjects with Advanced Refractory Cancers*, aims to enroll approximately 60 patients with several different types of advanced solid tumors.

"Bringing our novel product, INT230-6, into human testing is a major milestone for Intensity Therapeutics," commented President and CEO Lewis H. Bender. "Over the past few years our Company has demonstrated impressive tumor shrinkage in several murine models of cancers. INT230-6 eradicated large tumors, activated a systemic immune response and improved survival. Animals having a complete response acquired the capability to spontaneous clear re-challenges of the same cancer throughout the remainder of their lives, suggesting a protective effect similar to that of a vaccine. We are therefore excited to have initiated human testing. Our staff, investigators and clinical centers are enthusiastic about bringing patients our potentially life-saving product."

This unique Phase 1/2 study will first assess the safety of INT230-6 in tumors treated at the skin surface (e.g. breast, melanoma, head-and-neck and lymphoma). Subsequent patients receiving INT230-6 will include those with deep tumors (e.g. liver, pancreatic, colon, lung and others). Investigators will utilize image guidance to inject the tumors. Additionally, a cohort is planned to explore INT230-6 in combination with anti-PD1 agents. The study's primary goal is to demonstrate the safety of INT230-6. Secondary analyses will examine the efficacy of INT230-6 treatment via multiple parameters. The trial includes several adaptive components that will allow for adjustments in patient groups, dosing schedule and dose volumes administered.

"Our studies with INT230-6 have shown the ability to stimulate a strong T-cell response as a monotherapy. There is considerably enhanced activity using INT230-6 in combination with checkpoint inhibitors such as anti-PD-1 antibodies, while maintaining a favorable safety profile," said Chief Medical Officer Ian B. Walters, MD. "We are optimistic that our novel trial design can quickly detect evidence of direct tumor killing and immune system activation. Physicians

desperately need improved treatments for patients with advanced cancers that are not responding to approved immunotherapies. Intensity Therapeutics is grateful to the volunteers participating in our study and looks forward to collecting data on INT230-6 in different cancer types."

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 stimulated 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. at two hospitals associated with the University of Southern California (USC) and in Canada at the University Health Network (UHN) in Toronto. The principal investigator at USC is Dr. Anthony El-Khoueiry; the principal investigator at UHN is Dr. Lillian Siu. 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. 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 disperse throughout a tumor and diffuse 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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