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Intensity Therapeutics' INT230-6 Induces Immune Activation by Intratumoral Delivery as Reported in the Peer-Reviewed Journal OncoImmunology

- *INT230-6 shows ability to regress tumors and initiate a T cell mediated systemic immune response against cancer*

- *Data was generated by the National Cancer Institute's Vaccine Branch*
- *Increased efficacy observed when INT230-6 is combined with anti-PD-1 and anti-CTLA-4 antibodies in regression of injected tumors as well as un-injected tumors in the same animal.*

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 the company's proprietary therapeutic agents, today announced the publication in the journal *OncoImmunology* of results from nonclinical research conducted in partnership with the National Cancer Institute's (NCI) Vaccine Branch under a Cooperative Research and Development Agreement (CRADA). All results and data reported in the paper were generated at the NCI.

"The results of this study are noteworthy because they demonstrate the anti-cancer benefits of INT230-6 extend beyond direct killing of the injected tumor to fighting tumors throughout the body by immune activation," said Anja C. Bloom, Ph.D., first author and former visiting postdoctoral researcher at the NCI Vaccine Branch, who conducted the majority of the work at the NCI. "We believe this is the first time that the well-known agents comprising INT230-6, cisplatin and vinblastine showed induction of a durable immune activation. We believe this result is due to the intratumoral delivery mechanisms of the compound, which appears to cause cell death that also releases antigens to initiate an adaptive immune response."

The peer-reviewed paper entitled "Intratumorally delivered formulation, INT230-6, containing potent anticancer agents induces protective T cell immunity and memory," describes the immune response induced from direct injection of Intensity's lead product candidate, INT230-6, into subcutaneously implanted murine colon and orthotopic breast tumors. Treatment resulted in regression from baseline in 100 percent of tumors and complete response in up to ninety percent of mice. Studies that knocked out the mouse immune cells prevented complete responses, indicating a critical role of immune cells in treatment benefit. Mice with complete responses were protected from subcutaneous and intravenous re-challenge of the cancer, revealing that long-term immunological memory was induced by INT230-6.

Complete remission of the primary tumors was accompanied by shrinking and

disappearance of a number of untreated contralateral tumors when INT230-6 was combined with checkpoint inhibitors, demonstrating not only a local but also systemic immunological effect.

“Our work with Intensity Therapeutics was to evaluate the benefits of INT230-6 because of its delivery directly into solid tumors,” said Jay A. Berzofsky, M.D., Ph.D., Chief of the Vaccine Branch at the National Cancer Institute. “The results show that not only was complete regression achieved in a majority of injected tumors, but T cell immunity and immunological memory to the cancer were induced, associated with regression observed also in non-injected tumors and synergy when INT230-6 was combined with anti-PD-1 and anti-CTLA-4 antibodies. The treatment converts the tumor to an endogenous vaccine. Our results suggest that intratumoral approaches can be designed to provide a new strategy for effective immunotherapy of cancer.”

“Intensity Therapeutics entered into the CRADA with the NCI in 2014, and this peer-reviewed publication is the culmination of that research. The positive results described in the paper demonstrate the unique potential of our novel cancer treatment approach,” said Lewis H. Bender, Founder, President and Chief Executive Officer of Intensity Therapeutics. “We are currently evaluating INT230-6 in a Phase 1/2 clinical trial and have tested the drug in 15 different types of solid tumor cancers with promising results. The research with the NCI helped us design our clinical trial, and we recently presented clinical data at ASCO that indicate local treatment with INT230-6 alone in certain tumor types regresses injected tumors and initiates a systemic immune activation with results similar to the effects reported in our OncoImmunology paper. The nonclinical and clinical data generated to date increase our optimism about the potential of INT230-6 to kill tumors locally, activate the immune system, reduce the side effects associated with current systemic therapies and improve patient outcomes with achievement of a long-term, durable response for a number of cancers.”

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, cisplatin and vinblastine, 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℠ 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℠

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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