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Intensity Therapeutics Announces Publication of Research Reporting that Intratumoral Administration of INT230-6 Demonstrates Tissue Dispersive Properties, Tumor Regression and Elicits Systemic Adaptive Immunity

In vivo research published in a special issue of the *International Journal of Molecular Sciences*

WESTPORT, Conn.--(BUSINESS WIRE)-- [Intensity Therapeutics, Inc.](#), a clinical-stage biotechnology company pioneering a novel, immune-based drug approach to treat solid tumor cancers through direct tumor injection, today announced the publication of results from the Company's nonclinical research in the *International Journal of Molecular Sciences* (IJMS). The paper titled, "Intratumoral Administration of a Novel Cytotoxic Formulation with Strong Tissue Dispersive Properties Regresses Tumor Growth and Elicits Systemic Adaptive Immunity in *In Vivo* Models," was published in IJMS as part of a Special Issue titled *The Immune Landscape in Solid Tumors*. The Special Issue addresses various aspects of the molecular and cellular biology of immune cells in the context of tumors and invites experts in the field to contribute an original research article or a comprehensive review. The paper is available online (doi.org/10.3390/ijms21124493).

The paper describes the Company's lead product candidate, INT230-6, a novel combination of cisplatin and vinblastine formulated with a unique amphiphilic diffusion enhancer molecule (SHAO) that non-covalently interacts with payloads to increase intratumoral (IT) drug dispersion when injected into solid tumors. The data reported demonstrated that INT230-6 achieved greater inhibition of tumor growth and improved survival compared to the same drugs without enhancer given intravenously or IT. INT230-6 treatment increased the number of immune infiltrating cells within injected tumors. Animals demonstrating complete responses developed systemic immunity to the cancer. INT230-6 when combined with anti-programmed cell death protein 1 (PD-1), antibodies resulted in improved survival and increased rate of complete responses. INT230-6 induced significant tumor necrosis, which induced a systemic immune-based anti-cancer attack. This research demonstrates a novel, local treatment approach for cancer that minimizes systemic toxicity while stimulating adaptive immunity.

"The results reported in the paper provided the pre-clinical rationale to advance INT230-6 into clinical development," said [Lewis H. Bender](#) Founder, President and CEO of Intensity Therapeutics and lead author on the paper. "Our clinical research conducted to-date is consistent with the results of this paper; data suggests that the dispersion, tumor-killing and

immune activation properties of INT230-6 observed in mice are translating to humans. We are looking forward to initiating phase 2 clinical cohorts later this year combining INT230-6 with our partners' products, Merck's pembrolizumab and Bristol Myers Squibb's ipilimumab, in cancers with high unmet medical need."

About INT230-6

[INT230-6](#), Intensity's lead proprietary product candidate, is designed for direct intratumoral injection. INT230-6 was discovered using Intensity's proprietary DfuseRxSM technology platform. 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 for diffusion into cancer cells. In preclinical studies, INT230-6 eradicated tumors by a combination of direct tumor killing, release of tumor antigens and recruitment of immune cells to the tumor. Results generated by both the Company and the National Cancer Institute (NCI) showed 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 responses in animals with long-term protection from multiple re-challenges of the initial cancer and resistance to other cancers. The Company's research [published in the International Journal of Molecular Sciences](#) and jointly with the NCI as part of Intensity's collaborative research, [published in July 2019 in the Journal OncolImmunology](#) also showed strong synergy when INT230-6 was combined with anti-PD-1 and anti-CTLA-4 antibodies. INT230-6 is being evaluated in a Phase 1/2 clinical study ([NCT03058289](#)) in patients with various advanced solid tumors. There have been no dose limiting adverse events observed in patients to date, even when dosing into deep tumors in the lung and liver. Several patients demonstrated tumor shrinkage, symptomatic improvement, and evidence of cancer cell death and immune cell activation on tumor biopsy. In combination cohort with pembrolizumab the Company reported the safety of combination was comparable to INT230-6 monotherapy.

About Intensity Therapeutics

Intensity Therapeutics, Inc. is a privately held, clinical-stage biotechnology company pioneering a new immune-based approach to treat solid tumor cancers. Intensity leverages its DfuseRxSM 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. The Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch in 2014. The Company has a clinical collaboration with Merck Sharpe & Dohme (Merck) to evaluate the combination of INT230-6, Intensity's lead product candidate, and KEYTRUDA[®] (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced solid malignancies. The Company also has a clinical collaboration with Bristol Myers Squibb (BMS) to evaluate the combination of the Company's lead product, INT230-6, with BMS's anti-CTLA-4 antibody, Yervoy[®] (ipilimumab), in patients with advanced solid malignancies. 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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