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Intensity Therapeutics Doses First Patients with Combination of INT230-6 and Merck's Keytruda® in Phase 2 Studies

WESTPORT, Conn.--(BUSINESS WIRE)-- Intensity Therapeutics, Inc., a clinical-stage biotechnology company developing proprietary technology and products to kill tumors and increase immune system recognition of solid cancers, today announced that the first patients have been dosed with a combination of INT230-6, the Company's lead investigational product, and Keytruda® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy in Phase 2, KEYNOTE A10. The combination is being studied in a series of phase 2 expansion cohorts within IT-01, Intensity's ongoing international clinical study (NCT03058289).

Dosing these first patients initiates the second part of the Company's program with Merck. This new phase of the program evaluates the safety and efficacy of the combination in patients with four different types of cancer, colon (non-MSI high), pancreatic, and bile duct, which are cancers that are not immunogenic, as well as squamous cell carcinoma. The first combination cohort of INT230-6 with Keytruda enrolled seven patients with different types of advanced solid tumors and a number remain on study and continue to receive Keytruda. The acceptable safety profile from those patients allowed for the start of the phase 2 expansion arms.

"Bringing INT230-6 into phase 2 human testing in combination with Keytruda is another major milestone for Intensity Therapeutics," commented Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "Our preclinical and clinical data have demonstrated good safety for INT230-6 as a single agent or in combination with Keytruda. From the first cohort of patients we see evidence of clinical benefit. With the phase 1 escalation portion of our program complete, we are excited about treating patients earlier in their regimen with larger total amounts of INT230-6 especially in combination with Keytruda."

"The phase 2 portions of our Keytruda combination studies accrues patients with multiple tumor types," said Ian B. Walters, MD, Chief Medical Officer of Intensity Therapeutics. "We are optimistic that our trial design enables us to quickly evaluate safety and efficacy in patients with pancreatic, cholangiocarcinoma, and non and microsatellite unstable colorectal cancer, which are all difficult to treat and historically nonresponsive to a PD1/PDL1 antibody alone. Physicians desperately need better treatments for these patients and evidence of tumor response in any one of these patient populations would be validation of our approach of releasing tumor antigens derived from the patient's own tumors to enable an immune attack on the cancer, an effect that can be amplified by blocking a checkpoint signal."

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 DfuseRx^{SM} 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 Sciencesand jointly with the NCI as part of Intensity's collaborative research, published in July 2019 in the Journal OncoImmunology 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 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. 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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