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Intensity Therapeutics Reports Safety Results from First Cohort of the KEYNOTE A10 Combination Clinical Trial of INT230-6 and Keytruda®

Phase 2 cohorts evaluating the combination in patients with pancreatic cancer, cholangiocarcinoma, and microsatellite stable colorectal cancer to begin enrollment

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, today announced successful completion of the safety lead in portion of the IT-01 KEYNOTE A10 study arm (NCT03058289) that is testing the combination of INT230-6, the Company's lead investigational product, and Keytruda® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy.

The cohort treated seven patients with different types of advanced cancers that were amenable to superficial injections including triple negative breast cancer (n=3) Merkel cell carcinoma, chordoma, desmoid tumor, and soft tissue sarcoma. Patients's tumors were treated every two weeks for 5 doses with INT230-6 in combination with 200 mg of Keytruda every three weeks. All seven patients completed the 28 dose limiting toxicity (DLT) period with no DLT's or drug related serious adverse events. The safety profile appears to be similar to INT 230-6 monotherapy. Following completion of the dosing of INT230-6, patients continue on Keytruda monotherapy for up to 2 years. Scans will be collected regularly on patients to evaluate the efficacy of the combination.

The study steering committee, which is comprised of the principal investigators, reviewed the safety data and approved dosing into deep tumors as well as initiating phase 2 studies. The KEYNOTE A10 phase 2 studies will enroll patients with pancreatic cancer, microsatellite stable colorectal cancer and cholangiocarcinoma, These cancers are typically immunologically cold and historically non responsive to immunotherapies. Intensity also plans a fourth phase 2 cohort to test the combination in squamous cell carcinoma patients who have already failed a PD1/PDL1 agent.

"The confirmation of safety in our first combination cohort marks an important milestone in our evaluation of INT230-6 dosed with Keytruda," commented Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "We are excited to begin enrolling patients with cancers that are difficult to treat and historically nonresponsive to PD1/PDL1 antibodies alone. Patients with these cancers have limited therapeutic options and are in desperate need of better treatments."

"INT230-6 has previously demonstrated tumor cell killing and immune system activitation resulting in tumor regression in non-injected tumors in patients with several different tumor

types in the monotherapy portion of our ongoing Phase 1/2 study," said Ian B. Walters, MD, Chief Medical Officer of Intensity Therapeutics. "Considering the promising results INT230-6 has demonstrated as monotherapy and the encouraging safety observed thus far in combination with Keytruda, we look forward to moving into Phase 2, treating more patients with the combination and expanding upon our existing efficacy data. We believe our approach of releasing tumor antigens derived from the patient's own tumors to enable an immune attack on the cancer can be further amplified by blocking a checkpoint signal with Keytruda."

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.

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, releasing tumor antigens and recruitment of immune cells to the tumor. Results generated by 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 responder animals with long-term, durable protection from multiple re-challenges of the initial cancer and resistance to other cancers. The NCI and Intensity collaborative research, published in July 2019, showed that there was also 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.

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^{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 is also collaborating with Merck Sharpe & Dohme 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. For more information, please visit www.intensitytherapeutics.com and follow us on Facebook at https://www.facebook.com/IntensityTherapeuticsInc/ 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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