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Intensity Therapeutics Treats First Patient with Combination of INT230-6 and Merck's Keytruda®

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 patient has 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. The combination is being studied in a series of cohorts within IT-01, Intensity's ongoing Phase 1/2 international clinical study (NCT03058289).

The first part of the combination cohort of IT-01 expects to enroll approximately six patients with different types of advanced solid tumors in order to test safety of the combination. The second part will evaluate the safety and efficacy of the combination in several Phase 2 cohorts of patients with different types of cancer, including cancers that are not immunogenic.

"Bringing INT230-6 into human testing in combination with Keytruda is a major milestone for Intensity Therapeutics," commented Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "Our preclinical and clinical data to date have already demonstrated good safety for INT230-6 as a single agent, with evidence of patient benefit and immune activation in highly refractory cancer patients. We believe the immune activation potential of INT230-6 can be increased when combined with Keytruda, and are excited to have initiated human testing of the combination."

"Our Phase 1/2 study will continue to accrue patients with multiple tumor types in the INT230-6 monotherapy portion while concurrently exploring this combination," 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. Tumor types of interest in the Phase 2 cohorts include 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 improved 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, 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 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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