June 25, 2019

Intensity Therapeutics Announces Clinical Collaboration with Merck

- Phase 1/2 clinical trial to evaluate Intensity's INT230-6 in combination with KEYTRUDA® (pembrolizumab) for multiple solid tumor types

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 its proprietary therapeutic agents, today announced that it has entered into an agreement with Merck (known as MSD outside the United States and Canada), through a subsidiary, to evaluate the combination of Intensity's lead product candidate INT230-6 and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced solid malignancies including pancreatic, bile duct, squamous cell and non-MSI high colon cancers.

"Our research suggests our product, INT230-6, which enables improved recognition of cancer by the immune system, may exhibit additional effect when combined with anti-PD-1 antibodies," said Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "We are excited to be working with Merck, one of the world's leading cancer immuno-oncology companies, on our current Phase 1/2 clinical trial to explore the combination of INT230-6 and KEYTRUDA® in cancers with high unmet medical need. We are looking forward to initiating the combination portion of our program in the second half of this year."

Ian. B. Walters, M.D., Intensity's Chief Medical Officer, added, "We will be able to test the combination in a variety of difficult to treat tumors that historically have been non-responsive to checkpoint inhibitors. INT230-6 has demonstrated monotherapy activity, as well as a favorable safety profile, in patients with advanced cancers."

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 product candidate designed for direct intratumoral injection, is comprised of two proven, potent anti-cancer agents 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^{SM} 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^{SM} technology platform to create new 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 and unseen micro-metastases. 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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Source: Intensity Therapeutics, Inc.