April 14, 2020

Intensity Therapeutics Signs Clinical Collaboration Agreement with Bristol Myers Squibb for Advanced Solid Tumors

Phase 2 clinical trial to evaluate combination of INT230-6 and *Yervoy*® (ipilimumab)

WESTPORT, Conn.--(BUSINESS WIRE)-- Intensity Therapeutics today announced it has entered into a clinical trial collaboration agreement with Bristol Myers Squibb Company (NYSE: BMY). The program will evaluate the safety and efficacy of Intensity's lead product INT230-6, an investigational, novel and potent anti-cancer drug designed to directly kill cancer cells through intratumoral injection and improve immune cell recognition of cancer, when dosed in combination with Bristol Myers Squibb's Cytotoxic T Lymphocyte-Associated Antigen 4 (CTLA-4) immune checkpoint inhibitor Yervoy® (ipilimumab). The combination will be evaluated in patients with breast cancer, liver cancer and advanced sarcoma in a series of new cohorts within IT-01, Intensity's ongoing Phase 1/2 clinical trial. Intensity will sponsor and conduct the clinical trial and Bristol Myers Squibb will supply Yervoy for use in the study.

"We are excited to have entered into this clinical collaboration with Bristol Myers Squibb, a global leader and pioneer in immuno-oncology," said Lewis H. Bender, President and CEO of Intensity Therapeutics. "This new collaboration builds upon our other partnerships to evaluate the potential of INT230-6 in combination with immunotherapy. A joint publication with the National Cancer Institute last year, showed remarkable synergy with the combination of INT230-6 and CTLA-4 antibodies in nonclinical *in vivo* models. The ability to combine our drug in the clinic with Yervoy, may benefit patients with cancers that have high unmet medical need. Results from this collaboration could accelerate the timeline for clinical development and approval of our drug."

Ian. B. Walters, M.D., Intensity's Chief Medical Officer, added, "We will be able to evaluate the combination of INT230-6 and Yervoy in a variety of difficult-to-treat tumor types. To date, our Phase 1/2 study has produced solid evidence of activity with INT230-6 as a single agent, as well as a favorable safety profile, in patients with a variety of highly refractory, advanced cancers. In our studies we have also shown systemic immune activation and local recruitment of immune cells in treated tumors. The combination cohorts should enable further expansion of the immune response."

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℠ 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 responses in animals with long-term, protection from multiple re-challenges of the initial cancer and resistance to other cancers. The NCI and Intensity's collaborative research, published in July 2019 in the Journal OncoImmunogy 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.

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 is collaborating with Bristol, Myers Squibb (BMS) to evaluate the clinical combination of the Company's lead product, INT230-6, with BMS's anti-CTLA-4 antibody, Yervoy, in patients with advanced solid malignancies. 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20200414005152/en/

Investors:
Kerry Conlin
Stern Investor Relations
212-698-8685
kerry.conlin@sternir.com

Media:

Rebecca Drain
Intensity Therapeutics, Inc.
860-395-7636
rdrain@intensitytherapeutics.com

Source: Intensity Therapeutics