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Intensity Therapeutics Receives Fast Track Designation from U.S. FDA for Development of INT230-6 as Treatment for Relapsed or Metastatic Triple Negative Breast Cancer

WESTPORT, Conn., April 17, 2019 (GLOBE NEWSWIRE) -- 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 the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the Company's development program evaluating INT230-6 for the treatment of patients with relapsed or metastatic triple negative breast cancer (TNBC) who have failed at least two prior lines of therapy.

"We are extremely pleased to receive this Fast Track designation, which validates the potential of INT230-6 to treat patients with relapsed or metastatic triple negative breast cancer as a single agent," said Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "Finding improved therapies for this disease is a critical unmet medical need, and we look forward to working closely with the FDA this year to initiate a Phase 2 clinical study for this indication."

Approximately 15-20% of breast cancers test negative for estrogen receptors, progesterone receptors, and excess HER2 protein, qualifying them as triple negative. TNBC is considered to be more aggressive and have a poorer prognosis than other types of breast cancer, mainly because there are fewer targeted medicines. According to a study published in the *Journal of Clinical Oncology*, patients who fail two lines of therapy for TNBC typically progress within nine weeks. Those who have failed three lines progress within four weeks.

"This important regulatory designation is based on the promising data observed to date from use of INT230-6 in our breast cancer research," said Ian B. Walters, M.D., Chief Medical Officer of Intensity Therapeutics. "The Fast Track designation will allow us to engage robustly with the Agency to most effectively and efficiently develop our new cancer treatment approach, as well as help us determine other potential indications to pursue for INT230-6. To date, our ongoing Phase 1/2 trial has treated patients with more than 14 different types of advanced solid tumors including TNBC, and we look forward to evaluating use of INT230-6 in other areas for potential registration-enabling studies."

The FDA's Fast Track program facilitates development and expedites the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. A fast track drug must show some advantage over available therapy. Fast Track designation allows early and frequent communication between the FDA

and a drug company, often leading to earlier drug approval and access by patients. In addition, the Fast Track program allows for eligibility for Accelerated Approval and Priority Review, if relevant criteria are met.

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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