

Intensity Therapeutics Reports that INT230-6's Anti-cancer Mechanism is a Combination of Cell Death with Immune System Activation

- INT230-6 induces high rate of complete response in established mouse colon cancer models
- INT230-6 recruits immune cells and stimulates a potent tumor-specific T-cell response leading to durable protection
- Data to being presented at the 2016 AACR meeting

WESTPORT, Conn.--(BUSINESS WIRE)-- Intensity Therapeutics, Inc., a privately held biotechnology company developing proprietary immune cell-activating cancer treatments, announced that Chief Medical Officer Dr. Ian B Walters will be presenting mechanism of action and other data in a poster session at the American Academy of Cancer Research (AACR) meeting on April 19, 2016. The research being presented indicates that INT230-6 induces significant cancer cell death in the tumor microenvironment. Thereafter, eradication of the tumor by INT230-6 requires T lymphocytes and leads to a potent and durable systemic anti-cancer T-cell-dependent immunity against the tumor.

A series of preclinical studies conducted by the Company in collaboration with scientists from the Vaccine Branch at the National Cancer Institute (NCI) showed that following one cycle of five daily injections of low-dose INT230-6 into large mouse Colon26 tumors, 75% of the cancer cells die by day 3. Within 10 days of injection there was an increased influx of dendritic cells into the tumors, which are cells that can activate T-cells. Up to 80% of mice treated with INT230-6 experienced a complete response (CR) and became fully protected from re-inoculation challenges of the colon cancer. Both the treatment effect leading to CRs and the subsequent protective effect against re-inoculation decreased when CD4- and CD8-positive T-cells were depleted prior to treatment or re-challenge respectively. Protection was eliminated completely when both CD4 and CD8 T-cells were simultaneously depleted. Together the data indicate that the observed complete response and durable, vaccine-like anti-cancer effect of INT230-6 is a result of the direct cytotoxic nature of the drug and the formation of CD4- and CD8-positive immunological cell memory.

Chief Executive Officer <u>Lewis H. Bender</u> explained, "We plan to initiate clinical studies of INT230-6 as soon as possible. If our preclinical results translate in cancer patients, INT230-6 could represent a significant advance in the treatment of many types of solid tumor cancers, potentially providing oncologists with a less toxic means to destroy visible tumors, eliminate metastases and prevent disease recurrence."

Presentation Details

Poster Title: A novel immunotherapy, INT230-6, is able to induce high rates of complete and durable response in mice through a cytotoxic T-cell-dependent mechanism

Authors: Ian B. Walters MD and Lewis H. Bender of Intensity Therapeutics; Anja C. Bloom PhD, Masaki Terabe PhD, and Jay A. Berzofsky MD, PhD of the Vaccine Branch, Center for Cancer Research, NCI

Session Category: Immunology

Session Title: Immune Modulation from Non-Immunotherapy: Preclinical

Session Date and Time: Tuesday Apr 19, 2016 1:00 PM - 5:00 PM local time

Location: Ernest N. Morial Convention Center, New Orleans, LA, Halls G-J, Poster Section

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About INT230-6

INT230-6 is a novel, anti-cancer drug product able to disperse through tumors and diffuse into cancer cells. The product was identified from Intensity's DfuseRxSM platform technology. In *in vivo* preclinical models of severe cancer, INT230-6 treatment results in substantial improvement in overall survival compared to standard therapies. The product can completely clear large tumors in animal models. Complete responders have long-term protection even after multiple re-inoculations of the cancer. INT230-6 administration has shown an increased recruitment of immune cells to the tumor micro-environment. Intensity Therapeutics anticipates making an Investigational New Drug (IND) application to the U.S. FDA in 2016 to commence Phase 1 clinical studies.

About Intensity Therapeutics, Inc.

Intensity Therapeutics, Inc. is a biotechnology company whose mission is to greatly extend the lives of patients with cancer. Intensity Therapeutics is pioneering a new immune-based approach to treat cancer - *in situ* vaccination. The Company uses its DfuseRxSM platform technology to create new products capable of attenuating (killing) a tumor in a manner that allows for the adaptive immune system to recognize the cancer and attack tumors. Further information can be found at www.intensitytherapeutics.com

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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