

# Intensity Therapeutics Reports That INT230-6 Induces Protective T-Cell Immunity in Preclinical Models

- *INT230-6 induces high rate of complete response in established mouse models of severe colon cancer*
- *INT230-6 stimulates a potent tumor-specific T-cell response leading to durable protection*
- *Combination with PD-1 inhibitors improves INT230-6 performance*
- *Data to be presented at the 2017 AACR meeting*

WESTPORT, Conn.--(BUSINESS WIRE)-- [Intensity Therapeutics, Inc.](#), a privately held biotechnology company developing proprietary immune cell-activating cancer treatments, announced that tumor regression and immune activation data generated by the Company's lead drug, INT230-6, will be presented in a poster session at the American Academy of Cancer Research (AACR) meeting on April 5, 2017. The research being presented indicates that INT230-6 results in complete response of tumors in rodent models, induces protective T cell immunity and is synergistic with checkpoint inhibitors. Dr. Anja Bloom from the Vaccine Branch of the National Cancer Institute (NCI) and Lewis H. Bender, CEO of Intensity Therapeutics will present the poster presentation.

A series of preclinical studies conducted in collaboration with scientists from the Vaccine Branch at the NCI showed INT230-6 treatment leads to complete responses in rodents and a durable response. The subsequent protective effect against re-inoculation decreased when CD4- and CD8-positive T cells were depleted prior to treatment or re-challenge. The data indicate that the observed complete response and durable, vaccine-like anti-cancer effect of INT230-6 is immune mediated.

Intensity's Chief Executive Officer [Lewis H. Bender](#) explained, "The direct killing action and immune response data generated in rodent models from our lead drug INT230-6 are impressive. We hope these animal results translate into an equally potent response in our clinical study, IT-01 for INT230-6, which is now recruiting patients in both the U.S. and Canada. Should the protective T cell immunity occur in humans, then INT230-6 could represent an important advance in the treatment of certain 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:** Tumor cell death caused by INT230-6 induces protective T cell immunity  
**Session Category:** Clinical Research

**Session Title:** Innate Immunity to Generate Adaptive Immunity  
**Session Date and Time:** Wednesday Apr 5, 2017 8:00 AM - 12:00 PM  
**Location:** Convention Center, Halls A-C, Poster Section 28  
**Poster Board Number:** 14  
**Permanent Abstract Number:** 5660

### **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 DfuseRx<sup>SM</sup> platform technology and is currently in a clinical trial; IT-01. In preclinical studies conducted in by Intensity Therapeutics alone and in collaboration with the Vaccine Branch of the National Cancer Institute (NCI), INT230-6 administration was shown to increase recruitment of dendritic cells to the tumor micro-environment followed by T-cell activation. Treatment with INT230-6 in *in vivo* models of severe cancer completely cleared large tumors in animal models and generate substantial improvement in overall survival compared to standard therapies. Further, INT230-6 provided complete responders in these preclinical studies with long-term, durable protection from multiple re-inoculations of the cancer, demonstrating the potential to eliminate metastases and prevent disease recurrence.

### About Study IT-01

IT-01 is entitled *A Phase 1/2 Safety Study of Intratumorally Administered INT230-6 in Adult Subjects with Advanced Refractory Cancers*. The trial aims to enroll patients with different types of advanced solid tumor malignancies in a multicycle dosing regimen. IT-01 plans to include a cohort combining INT230-6 with an anti-PD-1 antibody. Currently the study is recruiting in the U.S. at the University of Southern California (USC) and in Canada at the University Health Network (UHN) in Toronto. The principal investigator at USC is Dr. Anthony El-Khoueiry; the principal investigator at UHN is Dr. Lillian Siu. The study's primary objective is to assess the safety and tolerability of multiple intratumoral doses of INT230-6. Secondary assessments are to understand preliminary efficacy of INT230-6. The study will characterize the pharmacokinetic profile of multiple doses of INT230-6 components. Exploratory analysis will characterize patient outcome, as well as evaluate various tumor and anti-tumor immune response biomarkers that may correlate with response. Data will be used to assess the progression free and overall survival in subjects receiving INT230-6. Further information can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT#03058289).

### **About the Vaccine Branch of the NCI**

The Molecular Immunogenetics & Vaccine Research Section (Berzofsky lab) within the Vaccine Branch studies, in animals and clinical trials, the immunology of antigen-specific T cell activation and regulation, and translation to strategies for design of vaccines for HIV, cancer, and viruses that cause cancer. Approaches include use of synergistic combinations of cytokines and TLR ligands in vaccines, approaches to increase CTL avidity, analysis of a new NKT cell immunoregulatory axis and regulatory circuit that inhibits tumor immunity and vaccine-induced immune responses against cancer and its interactions with other regulatory mechanisms and blockade of these to improve vaccine efficacy, strategies to induce mucosal immunity and mechanisms of mucosal trafficking and homing, epitope enhancement by sequence modification, and development of new cancer vaccines as well as AIDS vaccine strategies. Several basic discoveries are currently being translated into

clinical trials.

### **About Intensity Therapeutics, Inc.**

Intensity Therapeutics, Inc. is a clinical-stage 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. The Company uses its DfuseRx<sup>SM</sup> platform technology to create new products that disperse throughout a tumor and absorb into cancer cells. The drug products demonstrate in rodent models the capability of attenuating (killing) a tumor in a manner that allows for the adaptive immune system to recognize the cancer and attack distal tumors and micrometastases. Further information can be found at [www.intensitytherapeutics.com](http://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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