June 3, 2023

Intensity Therapeutics' INT230-6 Prolongs Survival Alone or in Combination With Ipilimumab in Adult Patients with Relapsed, Refractory, Metastatic Sarcomas

Compared To Synthetic Controls, INT230-6 Alone Extended Survival In Refractory Soft Tissue Sarcoma Subjects by Nearly 450 Days With Favorable Safety

INT230-6, a Locally Delivered Cytotoxic Treatment Leading to a Systemic Immune Response in Hot or Cold Tumors, Is A New Way To Treat Sarcoma

Results to be Presented Today, June 3, at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

WESTPORT, Conn., June 3, 2023 /PRNewswire/ -- Intensity Therapeutics, Inc. ("Intensity"), a clinical-stage biotechnology company focused on the discovery and development of proprietary, novel immune-based intratumoral (IT) cancer therapies designed to kill tumors and increase immune system recognition of cancers, today announced that data from its ongoing phase 1/2 clinical trial demonstrating the efficacy and tolerability of INT230-6, either as monotherapy or in combination with ipilimumab in patients with relapsed, refractory and metastatic sarcomas, will be presented this afternoon at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago and virtually from June 2-6, 2023.

Abstract Title: *Intratumoral INT230-6 (Cisplatin, Vinblastine, SHAO) alone or with ipilimumab (IPI) prolonged survival with favorable safety in adults with refractory sarcomas [Intensity IT-01; BMS#CA184-592].*
Presenter/First Author: Christian F. Meyer, MD, Johns Hopkins Sydney Kimmel Cancer Center
Session Title: Sarcoma
Poster Session Date and Time: Saturday, June 3, 2023, 1:15 PM – 4:15 PM EDT
Location: Exhibit Hall
Abstract Number: 11568
Poster number: 502

Copies of the presentation materials are available on Intensity's website on the publications, papers and posters page.

Sarcoma remains a very challenging cancer to treat and has historically proven resistant to checkpoint blockade. Novel approaches are needed for this patient population, and Intensity's data indicate that sarcoma is an attractive target for intratumoral injection. Christian Frederick Meyer, M.D., Ph.D., M.S. Assistant Professor of Oncology at the Sidney

Kimmel Cancer Center at Johns Hopkins University is an investigator for Intensity's phase 1/2 clinical trial and the presenter of the data at ASCO. Dr. Meyer has placed a number of his sarcoma patients into the study. INT230-6 has demonstrated significant survival prolongation and continues to be of great interest to a sarcoma oncologists, such as Dr. Meyer, especially given the data on immune ignition, as sarcoma is considered non-immunogenic and therefore largely unresponsive to immunotherapies.

"The prolonged survival of nearly 450 days compared to what would be expected in such a severe sarcoma patient population is a testament to the strength of our novel drug's potency," stated Lewis H. Bender, President and Chief Executive Officer of Intensity. "Causing significant tumor necrosis, immune infiltrates, uninjected tumor shrinkage and prolonged survival provides strong proof-of-concept evidence of our drug's mechanism of action and underscores the potential of INT230-6 to help metastatic sarcoma patients. As recent data readouts demonstrate, there remains a high unmet need for new therapeutic approaches to treat metastatic cancers in general. With that in mind, we have discussed our next steps with the U.S. Food and Drug Administration, drafted a protocol and look forward to advancing INT230-6 into a phase 3 trial for sarcoma patients."

Efficacy in subjects administered INT230-6, with or without ipilimumab, were compared to a synthetic control. The poster reports the median overall survival (mOS) and disease control rate (DCR equals the cases of stable disease, partial response and complete response divided by number of subjects) per the Response Evaluation Criteria in Solid Tumors (RECIST). Abscopal responses for INT230-6 alone were observed primarily in subjects dosed ≥ 40% of their total tumor burden (TTB). The DCR for the all-treated population (those who received at least one dose of INT230-6) was 93% for monotherapy and 86% for the ipilimumab combination. For the combination arm, one subject had yet to reach the first timepoint for SD at the time of data cut-off.

Study IT-01 was without a randomized control group; however, published clinical phase 1/2 basket trials in sarcoma report mOS ranging from 7.6 to 9.6 months (Jones et. al., Cancer Chemotherapy Pharmacology (2011) 68:423–429; Cassier et. al., Annals of Oncology 25: 1222–1228, 201; vi. Subbiah et. al., Scientific Reports | 6:35448 2016). Using the Subbiah study data and the Royal Marsden Hospital scoring system to predict survival for the sarcoma subjects from the IT-01 study, a synthetic Kaplan Meier (KM) control curve was generated. The overall survival of the control, all INT230-6 patients in sarcoma, including those receiving a cumulative dose of greater than 40% of their TTB, are shown in the below table.

Phase 1/2 studies	Control (Subbiah)	INT230-6 all	INT230-6 >40% TTB	INT230-6 + IPI
Median OS	205 days	649 days	Not yet reached	Not yet reached
Confidence Interval	-	(146, NR)		
Sample size	56	15	11	14

About INT230-6

INT230-6, Intensity's lead proprietary investigational product candidate, is designed for direct intratumoral injection. INT230-6 was discovered using Intensity's proprietaryDfuseRx℠ technology platform. The drug is composed of two proven, potent anti-cancer agents, cisplatin and vinblastine, and a penetration enhancer molecule (SHAO) that helps disperse potent cytotoxic drugs throughout tumors for diffusion into cancer cells. These agents remain

in the tumor resulting in a favorable safety profile. In addition to local disease control, direct killing of the tumor by INT230-6 releases a bolus of neoantigens specific to the patient's malignancy, leading to engagement of the immune system and systemic anti-tumor effects. Importantly, these effects are mediated without the immunosuppression of concomitant systemic chemotherapy.

About Intensity Therapeutics' Clinical Studies
INT230-6 has completed enrollment of over 200 patients in two phase 2 and phase 1 dose escalation clinical trials (NCT03058289 and NCT04781725) with various advanced solid tumors; IT-01 in metastatic disease, and IT-02 the INVINCIBLE study, in presurgical breast cancer. The Company has a clinical collaboration agreement with Merck Sharpe & Dohme (Merck) 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 pancreatic, colon, squamous cell and bile duct malignancies. The Company also has a clinical collaboration agreement with Bristol-Myers Squibb to evaluate the combination INT230-6 with Bristol-Myers Squibb's anti-CTLA-4 antibody, ipilimumab, in patients with advanced liver, breast and sarcoma cancers. Intensity is managing the individual combination arms separately with each respective partner via a joint development committee. The Company also executed agreements with the Ottawa Hospital Research Institute (OHRI) and the Ontario Institute of Cancer Research (OICR) to study INT230-6 in the INVINCIBLE study, a randomized controlled neoadjuvant phase 2 study in women with early stage breast cancer.

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℠ 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. In addition to the clinical collaborations, the Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch. For more information, please visit www.intensitytherapeutics.com and follow the Company 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.

Contact Information

Investor Relations Contact:
Rx Communications Group
Michael Miller
917-633-6086
mmiller@rxir.com

US Media Contact:
KOGS Communication
Edna Kaplan
781-639-1910
kaplan@kogspr.com

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