November 2, 2023

Intensity Therapeutics Presents Positive INT230-6 Data in Patients with Refractory Soft Tissue Sarcoma at the Connective Tissue Oncology Society Annual Meeting 2023

The disease control rate for subjects in the monotherapy was 93% for patients who received at least one dose of INT230-6

INT230-6 extended survival in refractory soft tissue sarcoma subjects by nearly 15 months when compared to a synthetic control group

In the study, INT230-6 was found to have a favorable safety profile and be well tolerated, with approximately 90% adverse events being grade 1 or 2

WESTPORT, Conn., Nov. 2, 2023 /PRNewswire/ -- Intensity Therapeutics, Inc. (Nasdaq: INTS), a clinical-stage biotechnology company focused on the discovery and development of proprietary, novel immune-based intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, today announced that safety, tolerability and efficacy data from IT-01, the company's ongoing Phase 1/2 clinical trial of INT230-6, either as a monotherapy or in combination with ipilimumab in patients with relapsed, refractory and metastatic sarcomas, was presented at the Connective Tissue Oncology Society 2023 Annual Meeting being held in Dublin, Ireland from November 1-4, 2023. The poster will be displayed for the duration of the Annual Meeting.

Abstract Title: INTRATUMORAL INT230-6 (CISPLATIN, VINBLASTINE, SHAO) ALONE OR WITH IPILIMUMAB PROLONGED SURVIVAL WITH FAVORABLE SAFETY AND IMMUNE ACTIVATION IN ADULTS WITH REFRACTORY SARCOMAS (NCT 03058289)
Presenter: Christian F. Meyer, M.D., Ph.D., M.S., Johns Hopkins Sydney Kimmel Cancer Center
Abstract Number: 1574238

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

Christian Frederick Meyer, M.D., Ph.D., M.S., is an Assistant Professor of Oncology at the Sidney Kimmel Cancer Center at Johns Hopkins University. Dr. Meyer is an investigator for Intensity's Phase 1/2 clinical trial of INT230-6 and the presenter of the data at CTOS. Dr. Meyer has placed a number of his sarcoma patients into the study due to the demonstrated significant survival prolongation effects of INT230-6.

"The data presented at CTOS highlights the true potential of INT230-6 as both a monotherapy or in combination with ipilimumab. INT230-6 showed an extensive increase in overall survival in metastatic patients over expected results for the heavily pretreated and diverse sarcoma population with an increase of nearly 15 months compared to a synthetic control. Approval of INT230-6, a locally delivered therapy, could be a paradigm-changing treatment for metastatic cancers," said Lewis H. Bender, President and Chief Executive Officer of Intensity. "INT230-6 can fully saturate a tumor with cytotoxic agents to begin apoptosis and cause necrosis when delivered intratumorally, resulting in immune activation consisting of dendritic and T-cell influx to the tumor all while maintaining a favorable safety profile. We have begun the preparations for a Phase 3 study of INT230-6 as a monotherapy and look forward to providing updates on the trial in the future."

IT-01, now complete, was an open-label Phase 1/2 study of INT230-6 in adults with locally advanced, unresectable or metastatic solid tumors, including sarcoma. INT230-6 dose was determined by a target injected tumor's diameter or volume and administered intratumorally once every two weeks for up to 5 doses with regular maintenance treatment either alone or in combination with ipilimumab at 3 mg/kg every three weeks for 4 doses. The primary endpoint was safety and approximately 90% of subjects had low grade adverse events.

Efficacy Data:

When compared to synthetic controls, INT230-6 alone extended survival in refractory soft tissue sarcoma subjects by approximately 14.9 months. Dosing higher amounts of INT230-6 relative to a patient's presenting total tumor burden showed increased survival when compared to the synthetic control. An INT230-6 dose relative to the presenting tumor burden of ≥ 40% further improved overall survival and the addition of ipilimumab may improve survival further.

- Median overall survival of INT230-6 was ~14.9 months longer than a synthetic control that was developed to predict survival of the enrolled sarcoma population.
- Median survival of synthetic control was about 6.8 months.
- The INT230-6 Disease Control Rate was 93% in subjects who received at least one dose of INT230-6 as monotherapy.

Safety Data:

Data to date indicate that INT230-6 has a favorable safety profile and is well tolerated.

- The majority of treatment-emergent adverse events (TEAEs) were grade 1 or 2 primarily localized pain, fatigue, and nausea.
- Two monotherapy and one combination subject experienced a grade 3 adverse event (AE)
- There were no reported grade 4 or 5 AEs.

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 proprietary DfuseRx℠ 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 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's lead product candidate, INT230-6, is in development for the treatment of patients with solid tumors, such as sarcoma and breast cancer. Intensity has a clinical collaboration agreement with Merck Sharpe & Dohme (Merck) to evaluate INT230-6 with pembrolizumab. In addition, the Company 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. Intensity has also executed agreements with the Ottawa Hospital Research Institute (OHRI) and the Ontario Institute of Cancer Research (OICR) to study INT230-6 in a randomized controlled neoadjuvant phase 2 study in women with early stage breast cancer (the INVINCIBLE study) (NCT04781725). Additionally, 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

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These statements include, but are not limited to, statements relating to the expected future plans, development activities, projected milestones, business activities or results. We have based these forward-looking statements on our current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements we make. These risks and uncertainties, many of which are beyond our control, include: the risk that the anticipated milestones may be delayed or not occur or be changed, as well as other risks described in the section entitled "Risk Factors" in the Company's SEC filings, which can be obtained on the SEC website at www.sec.gov. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management's current estimates, projections, expectations and beliefs. The Company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

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