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Intensity Therapeutics Provides Business Update Reflecting Progress in Phase 3 Sarcoma Program

FDA provides "Study May Proceed" letter for open-label, randomized phase 3 protocol in soft tissue sarcoma, and plans to initiate phase 3 study in first half of 2024

SHELTON, Conn., Jan. 3, 2024 /PRNewswire/ -- Intensity Therapeutics, Inc. ("Intensity" or the "Company") (Nasdaq: INTS), a late-stage clinical 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 a business update reflecting progress in its phase 3 sarcoma clinical program.

IND Submission for Phase 3

In the fourth quarter of 2023, the Company submitted a new Investigational New Drug ("IND") to the Food and Drug Administration ("FDA"). The submission included the phase 3 protocol for a superiority trial of the Company's lead product INT230-6 used as monotherapy compared to the standard of care drugs in 2nd and 3rd line treatment for certain soft tissue sarcoma subtypes. The FDA provided the Company a "Study May Proceed" letter for phase 3 within the 30 day period following the IND submission. The study is an open-label, randomized phase 3 trial expected to enroll 333 patients. For every three patients enrolled, two will receive INT230-6 and one will receive standard of care drug(s) chosen by the investigators depending on the type of sarcoma. The Company is working with its contracted vendors to initiate the phase 3 trial in the first half of 2024.

Manufacturing

In the fourth quarter of 2023, the Company successfully developed the phase 3 quality analytical methods for measurement of the key INT230-6 components, validated those methods and manufactured a clinical batch of the drug product that met specifications. During the fourth quarter, the Company requested and was granted a meeting that was held with the FDA to review the INT230-6 chemical manufacturing and controls ("CMC") for INT230-6. The CMC discussion focused on the tasks necessary to initiate the phase 3 study and future product registration as part of a potential New Drug Application (NDA). During the meeting, the Company and FDA agreed upon a plan for the CMC set of activities for the active pharmaceutical ingredients and the drug product (INT230-6) necessary for the NDA.

"The FDA's 'Study May Proceed' letter is another important milestone towards achieving our mission to develop a new, safer, and more effective way to treat cancer patients especially in the difficult to treat types such as sarcoma. A head-to-head comparison of INT230-6 as monotherapy locally delivered in metastatic sarcoma against the active, systemically-delivered standard-of-care drugs may be a first-of-its kind clinical trial," said Lewis H. Bender, President and Chief Executive Officer of Intensity. "Current standard-of-care drugs used for sarcoma after progression of the first line therapies require extensive safety monitoring. The standard of care drugs cause severe toxicities and provide median overall survival of only between 12 and 15 months depending on the drug and sarcoma subtype used. New and more effective ways to treat these patients are desperately needed."

In November of 2023 at the annual Connective Tissue Oncology meeting held in Dublin, Christian Frederick Meyer, M.D., Ph.D., M.S., an Assistant Professor of Oncology at the Sidney Kimmel Cancer Center at Johns Hopkins University and an investigator for Intensity's Phase 1/2 clinical trial of INT230-6, presented that when compared to a synthetic control[1], 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 a potential further increase in survival when compared to the synthetic control.

- Median survival of the synthetic control for subjects failing a median of 3 lines of prior therapy was about 6.8 months.
- Median overall survival of INT230-6 monotherapy (n=15) was 21.5 months.
- The INT230-6 Disease Control Rate[2] was 93% in subjects who received at least one dose of INT230-6 as monotherapy.

Data on INT230-6 generated in metastatic patients indicated that INT230-6 has a favorable safety profile and is well tolerated with the majority of treatment-emergent adverse events (TEAEs) being grade 1 or 2 primarily localized pain, fatigue, and nausea.

In September of 2023 the Company announced that the US FDA's Office of Orphan Products Development granted orphan-drug designation for the treatment of soft tissue sarcoma (STS) to the three active moieties comprising INT230-6, cisplatin, vinblastine sulfate, and the diffusion enhancer SHAO-FA (8-((2-hydroxybenzoyl) amino) octanoate).

About Soft Tissue Sarcoma
Soft tissue sarcoma is a broad term for cancers that start in soft tissues (muscle, tendons, fat, lymph and blood vessels, and nerves). These cancers can develop anywhere in the body but are found mostly in the arms, legs, chest, and abdomen. There are many types of sarcoma; however, the four most common are bone sarcoma (referred to as osteosarcoma), leiomyosarcoma, undifferentiated pleomorphic sarcoma (UPS) and liposarcoma. When sarcoma is metastatic prognosis is poor, even with chemotherapy. Each year, 12,000 people in the U.S. and 1,150 in Canada are diagnosed with soft tissue sarcomas. About 3,000 patients have bone sarcomas**.**

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 sulfate, 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 i.e. direct killing of the tumor by INT230-6, the dying tumor 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 immunosuppression that so often occurs with systemically delivered chemotherapy.

About Intensity Therapeutics

Intensity Therapeutics is a late-stage clinical biotechnology company that applies novel engineered chemistry to turn "cold" tumors "hot" by enabling its aqueous cytotoxic-containing drug product, INT230-6, to mix and saturate the dense, high-fat pressurized environment of the tumor. As a result of the saturation, Intensity's clinical trials have demonstrated the ability of INT230-6 to kill tumors and elicit an adaptive immune response within days of injection, representing a truly novel approach to cancer cell death that holds the potential to shift the treatment paradigm and turn many deadly cancers into chronic diseases. For more information about the Company, including publications, papers and posters about its novel approach to cancer therapeutics, visit www.intensitytherapeutics.com. 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 partnered 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 malignancies. The Company also partnered with Bristol-Myers Squibb to evaluate the combination of INT230-6 with Bristol-Myers Squibb's anti-CTLA-4 antibody, ipilimumab, in patients with advanced cancers. 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.

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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[1] A synthetic control is a construction of a weighted combination of reported data to which the treatment group is compared. This comparison is used to estimate what would have happened to the treatment group if it had not received the treatment. The synthetic control developed to predict survival of the enrolled IT-01 sarcoma population was based on the presenting biomarker data and used the Royal Marsden Hospital Index method for survival prediction.

[2] The disease control rate measures the percentage of patients with advanced or metastatic cancer who have achieved had stable disease, partial response or complete response while on a therapy.

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