January 10, 2025

Intensity Therapeutics Provides Business Update Highlighting Key Achievements with Lead Drug Candidate INT230-6

- *The US FDA, Health Canada, European Medicines Authority, and the Australian Therapeutic Goods Administration authorized the Company's global, randomized Phase 3 study (INVINCIBLE-3) in Metastatic Soft Tissue Sarcoma*
- *Twenty-three sites are currently contracted in the INVINCIBLE 3 study, and several sites have treated patients*
- *Seven Swiss sites are activated in the Phase 2 (INVINCIBLE-4) study for early-stage, operable Triple Negative Breast Cancer ("TNBC"), and several patients have been treated*

SHELTON, Conn., Jan. 10, 2025 /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 announces a business update highlighting key achievements with its lead drug candidate INT230-6.

Business Development

Discussions with multiple companies regarding potential strategic collaborations and licenses in various territories for INT230-6 initiated in 2024. While term sheets may be negotiated, there is no assurance that any ongoing discussions, negotiations, or due diligence processes will result in definitive agreements, partnerships, collaborations, or relationships.

Sarcoma INVINCIBLE-3

In July 2024, the Company initiated and dosed its first patient in a Phase 3 open-label, randomized study (the "INVINCIBLE-3 Study") testing INT230-6 as a monotherapy compared to the standard of care ("SOC") drugs in second-and third-line treatment for certain soft tissue sarcoma subtypes. This study has been authorized by the US FDA, Health Canada, the European Medicines Authority, and Australia's Therapeutics Goods

Administration. The trial is enrolling and being conducted in eight countries: the US, Australia, Canada, France, Germany, Italy, Poland, and Spain. Up to 62 sarcoma-focused hospitals and other centers are expected to participate from these countries.

In November 2024, the Company presented INT230-6 Phase 1/2 data in a late-breaking session at the 2024 Annual Connective Tissue Oncology Society Meeting (CTOS). These data showed a median overall survival ("mOS") of 21.3 months versus a synthetic control of 6.7 months, an increase in T-cell activation, and favorable safety profile for patients receiving INT230-6 alone. INVINCIBLE-3 continues recruiting with an expected enrollment of 333 patients with leiomyosarcoma, liposarcoma and undeferential pleomorphic sarcoma.

Breast Cancer INVINCIBLE-2 and INVINCIBLE-4

In October 2024, the Company, in collaboration with the Swiss Group for Clinical Cancer Research SAKK ("SAKK") in the INVINCIBLE-4 Study, a Phase 2 trial to treat patients with localized triple-negative breast cancer ("TNBC"), announced that the first patient has been dosed in the study.

In December 2024, Phase 2 data in presurgical breast cancer from the completed INVINCIBLE-2 study along with an overview of the ongoing INVINCIBLE-4 (SAKK 66/22), was presented at the 2024 San Antonio Breast Cancer Symposium (SABCS).

The Company's completed INVINCIBLE-2 Study, where INT230-6 was given alone in multiple tumor types including TNBC, showed the following:

- Tumor-killing properties at levels greater than 95% in some patients on a single intratumoral dose with systemic immune activation.
- Tumors larger than 2 cm showed significant necrosis in 74% of subjects at the time of surgery.
- Gene expression analysis showed a significant difference between baseline biopsies and surgical specimens. Pathway analysis identified genes associated with TCR signaling, B-cell and T-cell activation, with increasing effects in post-treatment samples (SABCS 2023 #PS16-03).
- The study demonstrated pathologic and immune priming effects of intratumoral cytotoxicity in traditional immune quiescent breast cancers, with a treatment that showed favorable safety and was well tolerated.
- INT230-6 patients had increases in CD4 T cells and NK cells within the tumor and associated changes in the diversity of T cell repertoire.

The INVINCIBLE-4 Study is a randomized open-label, multicenter study to determine the clinical activity, safety, and tolerability of INT230-6 in patients with tumors greater than two centimeters having early-stage, operable Triple Negative Breast Cancer ("TNBC"). These patients undergo standard-of-care neoadjuvant immunochemotherapy ("SOC") treatment, which consists of pembrolizumab, anthracyclines, carboplatin, cyclophosphamide, and paclitaxel (i.e. the Keynote-522 regimen). The primary endpoint is pathological complete response ("pCR") in the primary tumor and affected lymph nodes. Patients will be randomized one to one to receive a regimen of two doses of INT230-6 followed by SOC, or SOC alone. The study is expected to enroll 54 patients in up to 16 centers in Switzerland and France.

"The data from our prior studies and trial design has allowed INT230-6 to be authorized by the leading regulatory agencies globally to move into late-stage clinical trials. INT230-6 is being tested in metastatic and pre-surgical cancers, which highlights the broad potential for our new cancer treatment," said Lewis H. Bender, President and CEO of Intensity Therapeutics, "There are many risks and hurdles in drug development and advancing programs into phase 3 trials is an important achievement and a testament that reflects the expertise and dedication of our team. We are excited that contracts exist with nearly two dozen top sarcoma-centric hospitals in our Phase 3 study and nine sites in our Phase 2 presurgical breast cancer trial with seven activated. Several sites are enrolling and continue to recruit patients for both studies. Given the potential benefit of our new drug, we are working to establish partnerships that expedite product development and ultimate market access in the US and abroad."

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 mainly in the arms, legs, chest, and abdomen. There are many types of sarcomas; however, the four most common are bone sarcoma (referred to as osteosarcoma), leiomyosarcoma, undifferentiated pleomorphic sarcoma (UPS), and liposarcoma. According to SEER estimates, approximately 14,500 patients have metastatic liposarcoma, leiomyosarcoma, and undifferentiated pleomorphic disease at any one time in the US. When sarcoma is metastatic, the prognosis is poor, even with systemic chemotherapy.

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 comprised 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 and direct tumor killing, INT230-6 causes a release of a bolus of neoantigens specific to the malignancy, leading to immune system engagement and systemic anti-tumor effects. Importantly, these effects are mediated without immunosuppression, which often occurs with systemic chemotherapy.

About Triple Negative Breast Cancer in the Presurgical Setting

Approximately 11-17% of breast cancers test negative for estrogen receptors (ER), progesterone receptors (PR), and overexpression of human epidermal growth factor receptor 2 (HER2) protein, qualifying them as triple negative. TNBC is considered to be more aggressive and has a poorer prognosis than other types of breast cancer, because there are fewer available targeted medicines. Most patients with local TNBC typically receive immune/chemotherapy before surgery. Since the publication of Keynote-522, standard neoadjuvant treatment for TNBC includes systemic chemotherapy (anthracyclines, cyclophosphamide, paclitaxel, carboplatin) and the anti-PD-1 monoclonal antibody pembrolizumab. pCR rates are 65%, with rates lower in the larger-sized tumors. The toxicity of the Keynote-522 regimen is high, with 80% of patients experiencing grade 3 or higher treatment-related AEs, including treatment-related adverse events that lead to death in 0.5% of patients.

About Intensity Therapeutics
Intensity is a late-stage clinical biotechnology company whose novel engineered chemistry enables aqueous cytotoxic-containing drug formulations to mix and saturate a tumor's dense, high-fat, pressurized environment following direct intratumoral injection. 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 new approach to cancer cell death that holds the potential to shift the treatment paradigm and turn many deadly cancers into chronic diseases even for malignancies that do not respond to conventional immunotherapy. Intensity has completed two clinical studies and enrolled over 200 patients using INT230-6: a Phase 1/2 dose escalation study in metastatic cancers including sarcomas (NCT03058289), and a Phase 2 randomized control clinical trial in locally advanced breast cancer (the "INVINCIBLE-2 Study") (NCT04781725) in women without undergoing chemotherapy prior to their surgery. The Company initiated a Phase 3 trial in soft tissue sarcoma (the "INVINCIBLE-3 Study") (NCT06263231), testing INT230-6 as second or third-line monotherapy compared to the standard of care ("SOC") with overall survival as an endpoint. Intensity also initiated a Phase 2 study in collaboration with The Swiss Group for Clinical Cancer Research, SAKK (the "INVINCIBLE-4 Study") (NCT06358573) as part of a Phase 2/3 program evaluating INT230-6 followed by the SOC immunochemotherapy and the SOC alone for patients with presurgical triple-negative breast cancer. Pathological complete response ("pCR") is the primary endpoint. For more information about Intensity, including publications, papers, and posters about its novel approach to cancer therapeutics, visit www.intensitytherapeutics.com.

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 Company's expected future plans, cash runway, development activities, projected milestones, business activities or results. When or if used in this communication, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to the Company or its management, may identify forward-looking statements. The forward-looking statements contained in this press release are based on management's 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. These risks and uncertainties, many of which are beyond our control, include: the initiation, timing, progress and results of future preclinical studies and clinical trials and research and development programs; the need to raise additional funding before the Company can expect to generate any revenues from product sales; plans to develop and commercialize product candidates; the timing or likelihood of regulatory filings and approvals; the ability of the Company's research to generate and advance additional product candidates; the implementation of the Company's business model, strategic plans for the Company's business, product candidates and technology; commercialization, marketing and manufacturing capabilities and strategy; the rate and degree of market acceptance and clinical utility of the Company's system; the Company's competitive position; the Company's intellectual property position; developments and projections relating to the Company's competitors and its industry; the Company's ability to maintain and establish collaborations or obtain additional funding; expectations related to the use of cash and cash equivalents and investments; estimates regarding expenses, future revenue, capital requirements and

needs for additional financing; and 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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