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Intensity Therapeutics, Inc.'s Phase 3 INVINCIBLE-3 Sarcoma Study Selected for Presentation at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting

SHELTON, Conn., May 29, 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, announces that the Company will be presenting a Trials in Progress poster outlining its Phase 3 INVINCIBLE-3 clinical trial of INT230-6 for the treatment of metastatic soft tissue sarcomas. The poster will be shown at the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting held at McCormick Place in Chicago May 30-June 5, 2025.

The poster, titled, "A Multicenter, Randomized, Global Phase 3 Study to Assess the Efficacy and Safety of Intratumoral (IT) **IN**T230-6 (SHAO, **VIN**blastine, **Ci**splatin) as Monotherapy Compared with Standard of Care Systemic Chemotherapy in Adults with Locally Recurrent, Inopera**BLE**, or Metastatic Soft Tissue Sarcomas (STS)**(INVINCIBLE-3)**," will be presented by Sant P. Chawla M.D., Director, Sarcoma Oncology Center of Southern California, during the "Sarcoma" session to be held on Saturday May 31, 2025 from 9:30 AM to 12 PM on panel 66a. An abstract of the poster, which outlines the Company's Phase 3 study protocol, can be found here.

"The INVINCIBLE-3 trial is breaking new ground in metastatic sarcoma with a unique, new, investigational product, INT230-6. Following direct intratumoral injection, this drug product results in significant necrosis and the formation of cysts within tumors, with little residual cancer remaining in those injected tumors. A successful outcome of the INVICIBLE-3 study will require practicing physicians to think differently about setting dose and disease endpoints. INT230-6's dose per tumor is set by the tumor size. In this protocol, survival advantage is the gold standard upon which the efficacy of a novel investigational agent such as INT230-6 would be ultimately based," said Dr. Chawla.

"We have designed a unique Phase 3 protocol comparing our local therapy to the best

systemic standard of care based on our completed Phase 1/2 trial. In our first study, refractory, metastatic sarcoma patients whose disease continued to progress following a median of three prior lines of therapy received INT230-6 alone," said Lewis H. Bender, Intensity Therapeutics Founder, President, and CEO. "Those sarcoma patients showed immune engagement post-dose, uninjected tumors regressing, a disease control rate of 93%, and a median overall survival of 21.3 months with minimal treatment-associated adverse events. Eight regulatory agencies, including the U.S. FDA, have authorized the Phase 3 study. Until sufficient additional funding is obtained, new enrollment for the Phase 3 has been paused. We are continuing to treat the enrolled patients, maintain pharmacovigilance, monitor sites, and look forward to reinitiating recruitment as soon as sufficient resources are available."

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 immune system engagement and systemic anti-tumor effects. Importantly, these effects are mediated without immunosuppression, which so often occurs with systemic chemotherapy.

About INVINCIBLE-3

INVINCIBLE-3 is a study to evaluate a novel, new drug product administered intratumorally by an interventional radiologist or an equivalently trained physician using image guidance compared to systemically dosed second- or third-line US standard of care chemotherapy. Patients will be randomized 2 to 1 to INT230-6 or pazopanib, trabectedin, or eribulin (selection of SOC depends on the sarcoma subtype). As this is a survival study, there is no crossover allowed between US SOC and INT230-6. Disease progression will be determined by the World Health Organization (WHO) Criteria in conjunction with evaluation of the post-treatment scans. Dosing beyond radiographic progression is allowed should tumors have low levels residual cancer on scans post baseline. Participants will be prospectively stratified into 1 of 3 histologically defined aSTS strata: leiomyosarcoma, liposarcoma (dedifferentiated, myxoid, round cell and pleomorphic) and undifferentiated pleomorphic sarcoma

The participants will undergo in 4 phases: screening, treatment, maintenance, and follow-up in the study. Study visits, tumor and endpoint assessments will occur as indicated in the procedural outlines as part of a schedule of events. Important inclusion criteria include: histologically proven, unresectable, locally advanced, or metastatic STS only of the following Participant must have a pathology report indicating the diagnosis of their STS. Participants must have received at least 1 line of therapy for STS and must have progressed following anthracycline-based or alternative standard therapies, except if medically contraindicated or refused by the participant. A participant cannot have received more than 2 prior regimens for unresectable, locally advanced or metastatic STS. Participants must have measurable disease per RECIST 1.1 criteria. Participants must have at least 1 target tumor ≥ 2 cm suitable for injection using routine image guidance, measurable by CT or MRI.

Key exclusion criteria include: Prior primary or metastatic brain or meningeal tumors unless clinically and radiographically stable as well as off steroid therapy for at least 2 months. History of severe hypersensitivity reactions to US SOC agents and vinblastine or cisplatin or other products of the same class and their excipients. Histologically proven, unresectable, locally advanced or metastatic STS subtypes other than those specified, for example, excluded subtypes include liposarcoma (well differentiated), desmoid or dermatofibrosarcoma protuberans. Other prior malignancy, except for adequately treated basal or squamous cell skin cancer or superficial bladder cancer, or any other cancer from which the participant has been disease-free for at least 2 years.

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 the investigational new drug, 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 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.

Investor Relations Contact:
Justin Kulik
Justin@coreir.com
CORE IR
(516) 222-2560

Media Contact:
Jules Abraham
CORE IR
pr@coreir.com

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