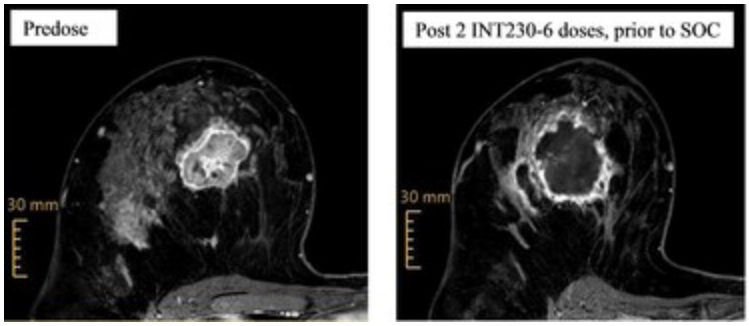
September 10, 2025

Intensity Therapeutics Reports INVINCIBLE-4, Presurgical Triple-Negative Breast Cancer Study Update

- *A pathological complete response ("pCR") has been observed in the first patient evaluated in Cohort A, where each patient receives two doses of INT230-6 eight days apart, followed by the standard of care immunochemotherapy ("SOC")*
- *Safety looks favorable in Cohort A*
- *Some INT230-6 patients begin to show localized skin irritation, and new patient enrollment has been paused to implement modifications to resolve the issue*
- *Patients being treated with INT230-6 continue to show significant necrosis after two doses of INT230-6 and prior to the initiation of the SOC, as shown in the photos below of a single patient's breast tumor scans*

SHELTON, Conn., Sept. 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 novel intratumoral cancer therapies that are designed to kill tumors and increase immune system recognition of cancers using its proprietary non-covalent conjugation technology, today provided an update on the INVINCIBLE-4 trial. A pathological complete response ("pCR") has been observed in the first patient evaluated in Cohort A, where each patient receives two doses of INT230-6 eight days apart, followed by the SOC. To date, there has been favorable safety in cohort A. However, some patients in Cohort A experienced localized skin irritation near the tumor. As a result, new patient enrollment has been paused to evaluate the data collected and to implement necessary adjustments prior to reopening accrual.



"While efficacy of INT230-6 is quite promising, and we are excited by the early radiological and pathological results, an essential aspect of any treatment for breast cancer patients is to have a good cosmetic result post-surgery," said Ursina Zürrer, M.D. Chief Physician for Genetic Counseling, Department of Medical Oncology and Hematology, Cantonal Hospital

Winterthur, Switzerland, and the Coordinating Investigator for the INVINCIBLE-4 Study. "We believe that the INT230-6 has the potential to make a positive impact on patients with triple-negative breast cancer from a safety and efficacy perspective. We expect to reinitiate the enrollment with a modified INT230-6 dosing regimen as soon as possible. The pause was a decision made with Intensity and not a directive from any regulatory agency."

"As was seen in our prior studies, tumor scans indicate high levels of drug absorption and significant tumor necrosis with evidence of immune activation before the initiation of the standard of care therapy, and we are excited that the first patient evaluated who received our drug had a pCR," said Lewis H. Bender, Intensity's President and CEO. "We plan to complete a data evaluation to determine the cause of the skin irritation and implement changes needed to eliminate or reduce the issue. Our objective is to reinitiate enrollment and complete the study as soon as possible. Intensity's ultimate goal is to provide patients with a new product that offers presurgical triple-negative breast cancer patients improved safety and a greater likelihood of having a pathological complete response, while also providing a good appearance post-surgery."

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 consists of two proven, potent anti-cancer agents, cisplatin and vinblastine sulfate, and a diffusion and cell penetration enhancer molecule ("SHAO") that conjugates non-covalently to the two payload drugs and facilitates the dispersion of the potent cytotoxic drugs throughout tumors, allowing the active agents to diffuse 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 the INVINCIBLE-4 Study

The INVINCIBLE-4 study is a Phase 2 non-comparative, hypothesis-driven randomized open-label, two-cohort multicenter study to analyze the clinical activity, safety, and tolerability of INT230-6 given before administration of the standard of care immunochemotherapy ("SOC") treatment in patients with early-stage, operable triple-negative breast cancer and SOC alone. The primary endpoint is the pathological complete response rate for the combination and the SOC alone. pCR is the absence of cancer at the time of surgery in the tumor and nodes. pCR is an FDA accelerated approval endpoint. Clinical evidence is strong that the risk of a patient's cancer returning is significantly reduced when there is a pCR at the time of surgery. The Swiss Medic and the European Medicines Agency authorized the initiation of the INVINCIBLE-4 Study in Switzerland and France. The SCI led study is also being done in collaboration with Unicancer (UCBG), the French referent cooperative group in breast cancer accredited by the French National Cancer Institute. The expected total enrollment is up to 54 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 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, the potential efficacy and safety of INT230-6 for patients with triple-negative breast cancer, 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; results observed from preliminary data are not necessarily indicative of final results and one or more of the clinical outcomes may materially change following more comprehensive reviews of the data and as more patient data becomes available, including the risk that unconfirmed responses may not ultimately result in confirmed responses to treatment after follow-up evaluations; the risk that product candidates that appear promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials; 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; our potential inability to satisfy the Nasdaq Capital Market's requirements for continued listing and be subject to delisting; 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 Annual Report on Form 10-K for the year ended December 31, 2024 and in the Company's subsequent 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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