July 15, 2026

Intensity Therapeutics, Inc. Restarts Patient Treatment in the Randomized, Presurgical Triple Negative Breast Cancer Phase 2 Clinical Trial (INVINCIBLE-4 Study)

First patients dosed in Switzerland

SHELTON, Conn., July 15, 2026 /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 announces that new patients have been administered INT230-6 in the INVINCIBLE-4 Study in Switzerland. The trial (NCT06358573) analyzes INT230-6 given before administration of the standard-of-care neoadjuvant immuno-chemotherapy ("SOC") and the SOC alone by using a 2-cohort design. The study evaluates the pathological complete response ("pCR") rates of the two cohorts relative to a null hypothesis, which is a pCR rate of ≤ 0.6. The success of each cohort in rejecting the null hypotheses will be evaluated.

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 early-stage, operable triple-negative breast cancer ("TNBC") who undergo SOC treatment and SOC alone. The primary endpoint is pCR in the primary tumor and affected lymph nodes. In the amended protocol, patients will be randomized to receive a regimen of one dose of INT230-6 followed by SOC, which consists of pembrolizumab, anthracyclines, carboplatin, cyclophosphamide, and paclitaxel, or to SOC alone. The INVINCIBLE-4 Study reopens following a pause in patient accrual to evaluate skin irritation issues seen in some patients. In March 2026, a protocol amendment was submitted to Swissmedic and the Swiss Ethics Committee to resume enrollment using a slightly lower drug-to-tumor volume ratio and a single injection of INT230-6. Prior to the pause, fourteen (14) patients were treated, seven (7) with the combination and (7) received the SOC alone. Patients receiving INT230-6 prior to the SOC reported a favorable trend towards much fewer overall grade 3 or higher adverse events and immune-related adverse events compared to those patients receiving the SOC alone. The

INVINCIBLE-4 Study is expected to enroll an additional 47 patients in Switzerland and France.

"Many TNBC patients undergoing SOC treatment alone fail to achieve a pathological complete response at the time of surgery, especially in larger tumor sizes. Early data indicates that INT230-6 has the potential to fill this unmet need for aggressive subtypes, such as TNBC, through its anti-cancer mechanisms of action that cause tumor cell necrosis and ignite an anti-cancer immune-based response," said Markus Joerger, MD-PhD from the Department of Medical Oncology and Hematology at Health Ostschweiz, Professor of Medicine at the University of Basel, Co-Chair of the SCI's Project Group for Developmental Therapeutics and coordinating investigator of the trial. "The ability for INT230-6 to induce necrosis and activate immune effects before a patient's surgery with reduction in toxicity would be a major advance for the treatment of breast cancer and potentially many other cancers."

"We are excited to have restarted our Phase 2 study in presurgical triple-negative breast cancer. Triple-negative is a deadly and aggressive form of breast cancer, and patients having local disease currently undergo a harsh six-month regimen whereby a small percentage can die from the SOC before their surgery," said Intensity Therapeutics' Founder, Chairman, and CEO, Lewis H. Bender. "We believe that the new dosing regimen can continue to show favorable overall safety, a meaningful improvement in the percentage of patients who achieve pCR, and ultimately an improved event-free survival."

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 non-covalently conjugates to the two payload drugs, facilitating the dispersion of potent cytotoxic drugs throughout tumors and 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 Triple Negative Breast Cancer in the Presurgical Setting

Approximately 11-17% of breast cancers test negative for estrogen receptors (ER), progesterone receptors (PR), and excess 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, mainly 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 only 63%, with rates generally lower in the larger-sized T2 to T4 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 that 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 SOC with overall survival as an endpoint. Intensity also initiated a Phase 2 study in collaboration with the Swiss Cancer Institute (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. 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 or review our SEC filings.

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 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, 2025 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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