March 12, 2026

Intensity Therapeutics, Inc. Provides Update on the Phase 2 Presurgical Triple-Negative Breast Cancer INVINCIBLE-4 Study

- *Preliminary observations of the INVINCIBLE-4 Study to date showed that five (5) out of seven (7) patients (71.4%) who received INT230-6 prior to standard of care ("SOC") ("Cohort A") achieved a pathological complete response ("pCR") whereas two (2) out of six (6) (33%) patients in the SOC arm alone ("Cohort B") achieved a pCR, with one patient still to be evaluated.*

- *Forty-four percent (44%) fewer grade 3 or higher Adverse Events ("AEs") were observed in Cohort A compared to Cohort B.*

- *A protocol amendment has been submitted to the Swiss Agency for Therapeutic Products ("Swissmedic"), Switzerland's regulatory authority, and the Swiss Ethics Committee to resume enrollment.*

SHELTON, Conn., March 12, 2026 /PRNewswire/ -- Intensity Therapeutics, Inc. (Nasdaq: INTS) ("Intensity" or "the Company"), a late-stage clinical biotechnology company focused on the discovery and development of proprietary cancer therapies using its non-covalent, drug-conjugation technology that creates drug products designed to kill tumors and increase immune system recognition of cancers, provided an update on the INVINCIBLE-4 Study. In September 2025, enrollment was paused by the Company due to skin irritations observed in Cohort A. In early March 2026, a protocol amendment was submitted to Swissmedic and the Swiss Ethics Committee to resume enrollment using a lower drug volume per tumor volume ratio and a single injection of INT230-6.

The SOC in the INVINCIBLE-4 Study is the Keynote-522 study regimen, a 6-month presurgical treatment consisting of pembrolizumab every three weeks, then paclitaxel, followed by carboplatin and 4 doxorubicin or epirubicin with cyclophosphamide. The INVINCIBLE-4 Study enrollment criteria is limited to patients with tumors sizes ≥ 1.5 cm, whereas the Keynote-522 study enrolled tumors > 1.0 cm. As a result, patients in the INVINCIBLE-4 Study, on average, have larger tumors than patients in the Keynote-522 study. Patients undergo the Keynote-522 regimen in an attempt to obtain a pCR, which has

been shown to significantly reduce the risk of disease recurrence. pCR is an endpoint that the U.S Food and Drug Administration ("FDA") and the European Medicines Agency could allow for an accelerated or conditional marketing approval.

Overall, fourteen (14) patients have been treated to date in the INVINCIBLE-4 Study, with seven (7) in each cohort. The expected total enrollment is up to sixty-one (61) patients. Preliminary observations for the fourteen patients treated to date are as follows:

pCR Data Observations

- Cohort A: A pCR was achieved in five (5) out of seven (7) patients (71.4%) who received injections of INT230-6 prior to SOC. Six (6) patients received two (2) injections and one patient, who achieved a pCR, received one (1) injection.

- Cohort B: A pCR was achieved in two (2) out of six (6) patients (33%) who received the SOC alone, with one patient still to be evaluated.

The pCR analysis is ongoing, and results are preliminary and early.

Safety Data Observations (through March 2, 2026)

- Cohort A: There has been a total of fourteen (14) grade 3 or higher AEs, only one (1) of which is considered a common immune-related side effect of checkpoint immunotherapy.

- Cohort B: There has been a total of twenty-five (25) SOC-related grade 3 AEs, of which four (4) are considered common or rare side effects of immune checkpoint inhibitors (three grade 3 and one grade 4).

The safety data for patients who received INT230-6 plus SOC remain favorable compared with SOC alone.

In the Company's first presurgical Breast Cancer study completed in 2023 (the "INVINCIBLE-2 Study"), fifty-eight (58) women received one (1) to three (3) injections of only INT230-6. Additionally, skin issues were rare, and surgery was performed without complications.

The Company expects presentation of more detailed results for the seven (7) Cohort A patients at a future oncology conference.

Lewis H. Bender, Founder, President & CEO, said, "The pCR data observations to date in the INVINCIBLE-4 study are promising, though preliminary and early. We are also pleased to see fewer total grade 3 or higher adverse events and fewer adverse events associated with checkpoint inhibitors when our drug is combined with immunochemotherapy in Cohort A than seen in Cohort B. The safety observed to date is consistent with our prior results using our drug with immunotherapy in mice[1] and humans, which have been presented at oncology conferences or published in peer-reviewed journals."[2]

Mr. Bender continued, "Triple-negative breast cancer is one of the most aggressive and difficult to treat subtypes. As reported in the Keynote-522[3] study, 77% of patients using the

current SOC immunochemotherapy regimen alone have grade 3 or higher systemic adverse events, and 0.5% of patients died from the regimen. Reducing the total number of grade 3 or higher adverse events by 44%, especially immune-related adverse events, and the potential for a higher pCR rate with INT230-6 prior to SOC, could be life-saving for patients. With the amendment now filed with Swissmedic, we look forward to dosing the next patient."

About Triple Negative Breast Cancer in the Presurgical Setting

Women with aggressive forms of breast cancer, such as Triple Negative Breast Cancer ("TNBC"), are often counseled to undergo pre-surgical (neoadjuvant) systemic therapy in advance to reduce the risk of the disease returning. Having a pathological complete response, meaning the absence of live cancer at the time of surgery, has been shown to result in a lower risk of disease recurrence from 50% to 16% at 5 years. Approximately 11 to 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. There are approximately 56,000 new cases of TNBC in the US and 420,000 worldwide diagnosed each year, 85% of which are local to the breast. 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 immunochemotherapy before surgery. Since the publication of Keynote-522, the standard neoadjuvant treatment for TNBC includes systemic chemotherapy (anthracyclines, cyclophosphamide, paclitaxel, carboplatin) and the anti-PD-1 monoclonal antibody pembrolizumab. pCR rates range from 50 to 65%, depending on tumor size. Rates are generally lower in the larger-sized tumors or with lymph node metastasis. The toxicity of the Keynote-522 regimen is high, with 77% 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 a Potential INT230-6 Approval Pathway in the Presurgical Setting

The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions and that fill an unmet medical need based on a surrogate endpoint. pCR is an accepted FDA accelerated approval criterion for approval in high-risk breast cancer, such as TNBC subtype. Pathological complete response is defined as the absence of residual invasive and in situ cancer after evaluation of the completely resected breast specimen and lymph nodes following completion of neoadjuvant systemic therapy. If a product is approved using pCR, companies must still seek full approval using event-free survival as an endpoint.

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 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 SOC immunochemotherapy 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 sixty-one (61) 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 Group for Clinical Cancer Research, formerly SAKK, now 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, 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.

Investor Relations Contact:

Justin Kulik
CORE IR
coreirteam@coreir.com
(516) 222-2560

Media Contact:

Matt Cossel
CORE IR
pr@coreir.com

[1] Bloom, Bender, OncoImmunology June 2019
[2] Thomas_ASCO_2022_poster
[3] Shmid_NEJM_2020;

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