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Intensity Therapeutics Highlights 2025 Milestones and Outlines 2026 Strategic Priorities

Peer-reviewed clinical validation, strengthened balance sheet, and disciplined execution position the Company for 2026

SHELTON, Conn., Jan. 13, 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, today highlights key milestones achieved during 2025 and outlines strategic priorities for 2026.

2025 Key Highlights and 2026 Outlook and Strategic Priorities

- **INVINCIBLE-4 Study:** *Phase 2 randomized open-label, multicenter study to analyze the clinical activity, safety, and tolerability of INT230-6 given before administration of the standard of care ("SOC") treatment in patients with early-stage, operable triple-negative breast cancer and SOC alone.*
    - In September 2025, a pathological complete response was observed in the first patient evaluated in Cohort A, where each patient receives one or two doses of INT230-6 eight days apart, followed by the SOC. Some patients in Cohort A began to experience localized skin irritation, prompting a temporary pause in new patient enrollment. As a result, the protocol is being modified to administer one or two doses at lower volumes for each tumor size.

    - In December 2025, early observations data from the INVINCIBLE-4 Study were presented at the San Antonio Breast Cancer Symposium, showing favorable safety, with 50% fewer grade 3 or higher adverse events observed in the INT230-6 cohort compared to the standard of care neoadjuvant chemotherapy alone cohort. The INVINCIBLE-4 study was initiated in late 2024, and 14 patients have been treated, with 7 in each cohort.

    - The Company plans to file a protocol amendment with the regulatory agencies for this revision in dosing in the first quarter of 2026, and expects to reinitiate

enrollment for the now 61-patient study in the first quarter of 2026, as seven additional patients will be added to cohort A.

- **INVINCIBLE-3 Study:** *Phase 3 open-label, randomized study testing INT230-6 as monotherapy compared to the SOC drugs in second- and third-line treatment for specific soft tissue sarcoma subtypes.*
    - In March 2025, the Company paused new site activations and patient enrollments due to funding constraints. Before this pause, the trial had enrolled 21 patients. The Company continues to treat patients enrolled in this study, maintain the database, conduct pharmacovigilance, and conduct other study-related activities in cooperation with its third-party contract research organizations at significantly reduced ongoing costs during this pause.

    - The Company has prioritized reinitiating patient enrollment and site activations during 2026 once sufficient funding is obtained.
- **Potential New Phase 3 Breast Cancer Study:** *The clinical study could be with INT230-6 plus standard of care, potentially also using biomarkers to assess the need for anthracyclines (doxorubicin) for the treatment of neoadjuvant Triple Negative Cancer (assuming sufficient funding has already been obtained for the reinitiation of the Phase 3, sarcoma INVINCIBLE-3 Study)***.**
    - If safety and efficacy trends continue in the INVINCIBLE-4 Study, a Phase 3 clinical study design in the US and other countries using INT230-6 with the current standard of care may be initiated contingent on obtaining sufficient incremental funding.
- **Peer-Reviewed Publication in a Lancet journal: Validate Clinical Potential**
    - In October 2025, Intensity announced publication of its Phase 1/2 clinical study evaluating INT230-6 in the *Lancet Discovery Science* journal, *eBioMedicine (volume 121)*. The manuscript reported a 75% disease control rate and a median overall survival of 11.9 months in patients with advanced solid tumors, with a median overall survival of 21.3 months observed in a subset of sarcoma patients. At least 20% of patients receiving a dose greater than 40% of their total tumor burden had abscopal effects where uninjected tumors shrank. Exploratory analyses further demonstrated potential to improve disease control rates and overall survival, especially when treating higher percentages of tumor burden. There was also evidence of systemic immune engagement, reinforcing INT230-6's differentiated mechanism of action.

    - During 2026, the Company will continue to pursue an aggressive peer-reviewed publications strategy for its completed metastatic and breast cancer studies.
- **Strengthened Balance Sheet, Extended Runway into the Second Quarter of 2027:**
    - The Company raised over $20 million in gross proceeds during 2025 through two public offerings, one registered direct offering, and ATM issuances. These successful capital-raising efforts strengthened Intensity's balance sheet and extended its current operating runway into the second quarter of 2027, providing flexibility to advance certain clinical programs without near-term financing pressure.

    - The Company plans to maintain a disciplined operating approach in 2026 and will seek to opportunistically raise additional capital during 2026 to reinitiate patient enrollment and site activations in the INVICIBLE-3 Study, and to potentially

initiate a new Phase 3 Breast Cancer Study.

- **Business Development:** Continuing to pursue discussions with potential pharmaceutical partners to potentially accelerate the development and commercialization of our new drug.

Intensity Therapeutics Founder, President, and CEO Lewis H. Bender stated, "We enter our next phase of development with a clinically validated scientific foundation and a capital position that supports disciplined execution. A peer-reviewed publication in *eBioMedicine, a Lancet Discovery Science* journal, reinforced the clinical potential of INT230-6. At the same time, our successful capital raising efforts provided the resources to advance our programs well into 2027. Our focus remains on generating high-quality clinical data, additional peer-review publications, advancing regulatory engagement, and allocating capital with intention as we progress INT230-6 across multiple development pathways, in an attempt to build long-term shareholder value through consistent execution."

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 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 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, 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. 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 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.

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