December 11, 2025

Intensity Therapeutics, Inc. to Present Two Posters at the 2025 San Antonio Breast Cancer Symposium

- *Poster PS5-08-16 Reports Early Observations from the INVINCIBLE-4 Study, an Ongoing Randomized, Presurgical Phase 2 Clinical Trial for Triple Negative Breast Cancer continue to show favorable safety*
  - *50% fewer grade 3 or higher Adverse Events were observed in the INT230-6 cohort compared to the Standard of Care ("SOC") neoadjuvant chemotherapy alone cohort.*
- *Poster PS4-10-15 Describes An Overview of a Potential Phase 3 Clinical Study Design with INT230-6 plus standard of care with and without the toxic anthracycline, doxorubicin*

SHELTON, Conn., Dec. 11, 2025 /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, announces it will present two posters at the San Antonio Breast Cancer Symposium ("SABCS"), in San Antonio, TX being held at the Henry B. Gonzalez Convention Center.

On Friday, December 12, 2025 at 12:30 PM CST, Andreas Müller, M.D., from the Department of Medicine at the Kantonsspital Winterthur, Switzerland and Head of the Breast Center will present on behalf of the Swiss Cancer Institute abstract #1589 PS5-08-16, titled, *Intratumoral Injections of INT230-6 Prior to Neoadjuvant Immuno-chemotherapy in Early-Stage Triple Negative Breast Cancer (TNBC): Early observations from INVINCIBLE-4-SAKK 66/22 (NCT06358573), a Phase II Randomized Clinical Trial.* Today, December 11, 2025 at 5 PM CST, Lewis H. Bender, M.S., M.A., M.B.A., Intensity Therapeutics Founder, President and CEO, will present abstract #801 Poster PS4-10-15, titled**,** *Accelerating an Anthracycline-Free Future: A New Drug in Clinical Testing Offers Patients Hope for Safer, More Effective Breast Cancer Therapy Combinations*.

INVINCIBLE-4 Study Observations

The INVINCIBLE-4 study was activated in 2024. Fourteen patients have been treated to date

with 7 in each cohort. Observations to date include the following:

- The safety data for the patients who received INT230-6 plus SOC ("Cohort A"), continues to be favorable compared to the standard of care ("SOC") alone ("Cohort B")
  - Seven patients have been treated per cohort (14 patients total); there were nine grade 3 or higher adverse events in the INT230-6 plus SOC and 20 events in the SOC alone through November 10th (see Figure below)

		Cohort A - Experimental (N=7)			Cohort B - SOC (N=7)		
SOC	**Term**	**Grade 3**	**Grade 4**	**Overall**	**Grade 3**	**Grade 4**	**Overall**
Blood and Lymphatic System Disorders	Anemia				1 (14.3 %)		1 (14.3 %)
	Febrile neutrogenia	2 (28.6 %)		2 (28.6 %)	2 (28.6 %)		2 (28.6 %)
Ear and Labyrinth Disorders	Vertigo				1 (14.3 %)		1 (14.3 %)
General Disorders and Administration Site Conditions	Fatigue				1 (14.3 %)		1 (14.3 %)
	Injection Site Reaction	4 (57.1 %)		4 (57.1 %)			
Infections and Infestations	Catheter Related Infection				1 (14.3 %)		1 (14.3 %)
	Infected Seroma				1 (14.3 %)		1 (14.3 %)
	Skin Infection				1 (14.3 %)		1 (14.3 %)
	Urinary Tract Infection	1 (14.3 %)		1 (14.3 %)			
Investigation	Alanine Aminotransferase Increased				1 (14.3 %)		1 (14.3 %)
	Creatinine Increased				1 (14.3 %)		1 (14.3 %)
	GGT Increased				1 (14.3 %)		1 (14.3 %)
	Neutrophil Count Decreased		2 (28.6 %)	2 (28.6 %)	1 (14.3 %)	2 (28.6 %)	3 (42.9 %)
Metabolism and Nutrition Disorders	Anorexia				1 (14.3 %)		1 (14.3 %)
Neoplasms Benign, Malignant and Unspecified (incl. Cysts and Polyps)	Disease Progression				1 (14.3 %)		1 (14.3 %)
Nervous System Disorders	Guillain-Barre Syndrome				1 (14.3 %)		1 (14.3 %)
	Imunotherapy Related Encephalitis					1 (14.3 %)	1 (14.3 %)
Renal and Urinary Disorders	Chronic Kidney Disease				2 (28.6 %)		2 (28.6 %)
TOTAL		**7**	**2**	**9**	**17**	**3**	**20**

A patient with a 2.2 cm tumor who received one dose of INT230-6 showed skin irritation at the time of surgery. However, skin and adipose tissue necrosis on MRI scans were observed in some patients who received two doses, thereby requiring more surgery. As a result, the protocol is being modified to administer a single dose at lower volumes for each tumor size. If tumor necrosis is observed on MRI after the first dose of INT230-6 prior to the start of SOC, then a second dose will not be made.

<u>Potential Phase 3 Clinical Study Design</u>

If safety and efficacy trends continue in the INVINCIBLE-4 Study, a Phase 3 clinical study

design may include a treatment arm using INT230-6 and SOC without anthracycline compounds such as doxorubicin, a highly cardiotoxic agent. Doxorubicin is often referred to by patients and physicians as "the red devil" because of its red color and harsh effects.

In today's presentation, Mr. Bender discusses a potential Phase 3 clinical study concept using INT230-6 with SOC with and without doxorubicin compared to SOC alone . Currently, the SOC treatment includes immunotherapy (pembrolizumab), an anthracycline (usually doxorubicin), carboplatin, cyclophosphamide, and taxane. Depending on the strength of the pCR data from the INVINCIBLE-4 Study and a lead-in cohort of patients in a potential Phase 3 trial, a three-arm randomized, controlled Phase 3 trial could be 1) INT230-6 with SOC, 2) current SOC, and 3) INT230-6 with SOC without the anthracycline.

Christine Handy, a patient advocate and co-author on the poster number PS4-10-15 noted, "I have experienced permanent cardiotoxicity using the red devil, doxorubicin, when treated for my breast cancer and know full well how that agent can disrupt the lives and health of those fighting cancer. Patients can be harmed by the treatment for this potentially deadly disease and often have to make a difficult choice as some fear the harmful effects of therapy as much as the cancer itself. I am encouraged by companies such as Intensity Therapeutics with new concepts for improving safety and efficacy for patients and am excited by the early observations of this new and novel drug treatment."

Mr. Bender concluded, "Triple Negative Breast Cancer is one of the most aggressive and difficult to treat breast cancer subtypes. While our INVINCIBLE-4 Study is still early, we are encouraged by the observed safety as reported in the PS5-8-16 poster and pCR results received to date when our drug is combined with SOC immunochemotherapy. These new safety results are consistent with the data from pre-clinical and clinical data when our drug is combined with immunotherapies. We look to restart patient enrollment in INVINCIBLE-4 study using the modified dosing regimen to improve our results as soon as possible. Should the safety and pCR results remain favorable, we plan to approach regulatory authorities with a Phase 3 study design that could yield a safer, more effective presurgical dosing regimen with good cosmetic outcomes for patients. Subject to regulatory agreement, using pCR as the surrogate endpoint could allow for an accelerated approval of a TNBC regimen without the red devil in a timeframe sooner than current trials that are evaluating event free survival."

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 recurrence. Approximately 11-17% 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, the majority 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 immune/chemotherapy 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 are 65%, with rates generally lower in the larger-sized tumors or with lymph node metastasis. 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 a Potential INT230-6 Approval Pathway in the Presurgical Setting

The U.S Food and Drug Administration ("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. Pathological complete response ("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 complete 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 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 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.

About Christine Handy

Christine Handy is an American model, author, motivational speaker, Executive producer and breast cancer survivor. She has been a print model for over 40 years. Handy was diagnosed with an aggressive form of breast cancer on October 1, 2012. She experienced 28 rounds of chemotherapy and a double mastectomy. Handy's 2016 novel *Walk Beside Me* is a fictionalized story of the ordeal of a successful model who receives a breast cancer diagnosis and several rounds of chemotherapy using doxorubicin. It was a national bestseller. In May of 2025, the independent film, *Hello Beautiful,* based on Christine's life*,* won the Golden Palm Best Picture Award at the prestigious and influential 25th Annual Beverly Hills Film Festival.

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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