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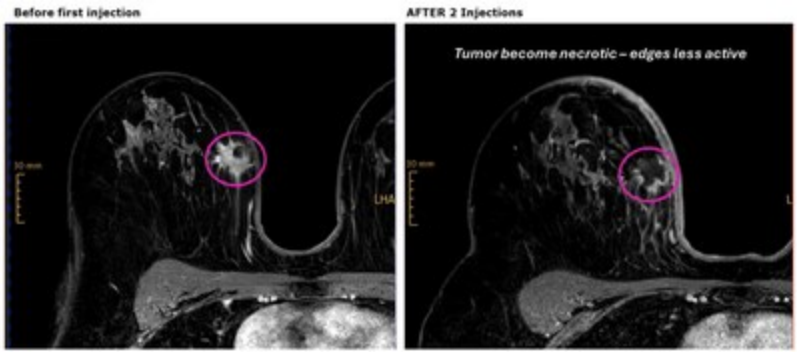
Intensity Therapeutics, Inc. Announces Patients Receiving INT230-6 Prior to the Start of Standard-of-Care May Achieve High Levels of Tumor Necrosis in the Ongoing Randomized Controlled Phase 2 INVINCIBLE-4 Study

SHELTON, Conn., June 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, novel immune-based intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, announces first few patients receiving INT230-6 achieved high levels of necrosis after 8 days in the Phase 2, INVINCIBLE-4 study, before they initiated the standard-of-care regimen as shown in Figure 1.



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 standard of care neoadjuvant immunochemotherapy ("SOC") treatment and SOC alone. The primary endpoint is pathological complete response ("pCR"), i.e., the absence of live cancer in the primary tumor and affected lymph nodes. Patients are being randomized one-to-one to receive either a regimen of two doses of INT230-6 followed by SOC, which consists of pembrolizumab, anthracyclines, carboplatin, cyclophosphamide, and paclitaxel (i.e., the Keynote-522 regimen), or SOC alone. The study is recruiting patients in Switzerland and France and is expected to enroll 54 patients.

"We are encouraged to see high levels of tumor necrosis from the MRI scans and evidence of tumor inflammation after two INT230-6 injections and before initiation of the SOC in our first patients," 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 are encouraged that these patients achieved such a good response to INT230-6 prior to their beginning the Standard immune-chemo regimen and look forward to continuing enrollment in the study."

"We are excited to see that INT230-6 is achieving meaningful levels of necrosis in patients with evidence of immune activation. TNBC Patients who have no live cancer in their tumor or nodes at the time of surgery have a significantly improved event-free survival advantage compared to those who do not have a pathological complete response. TNBC patients risk their lives to achieve a pCR, and about forty percent fail to achieve the desired result. We look forward to seeing the pathological complete response data being generated by our partners at SAKK and Unicancer," said Lewis H. Bender, President and CEO of Intensity.

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 is comprised of two proven, potent anti-cancer agents, cisplatin and vinblastine sulfate, and a diffusion and cell penetration enhancer molecule ("SHAO") that helps disperse potent cytotoxic drugs throughout tumors for diffusion 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

Women with aggressive forms of breast cancer, such as 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 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

About SAKK

The Swiss Group for Clinical Cancer Research (SAKK) is a decentralized academic research institute that has been conducting clinical trials of cancer treatments in all major Swiss hospitals since 1965. It federates a large network of research groups with a Competence Center in Bern in charge of coordinating the clinical operations. It also works with selected cooperative groups abroad, particularly on rare forms of cancer. SAKK's aim is to advance existing cancer treatments, investigate the efficacy and tolerability of new treatments (radiotherapy, medicines and surgery), and set new standards in treatment. 22 Swiss hospitals are full members of SAKK. Research activity is funded by federal subsidies provided by the State Secretariat for Education, Research and Innovation (SERI) and financial support from other partner organizations such as the Swiss Cancer League and the Swiss Cancer Research Foundation. Further information can be found at https://www.sakk.ch/en.

About Unicancer

The Unicancer French breast intergroup (UCBG) is the French referent cooperative group in Breast Cancer. The French National Cancer Institute (INCa) accredited the group in 2013, thus acknowledging its academic excellence and operational capability. Since its creation, the group has conducted more than 40 national and international multicenter clinical trials, as well as various translational research projects.

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 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; 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 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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