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Intensity Therapeutics, Inc. and The Swiss Group for Clinical Cancer Research SAKK Present Phase 2 Data in Presurgical Breast Cancer from the completed INVINCIBLE-2 Study, and an Overview of the Ongoing Randomized, Presurgical Triple Negative Breast Cancer Phase 2 Clinical Trial, INVINCIBLE-4 (SAKK 66/22), at the 2024 San Antonio Breast Cancer Symposium (SABCS)

Enrollment is ongoing and seven sites in Switzerland have been activated

SHELTON, Conn. and BERN, Switzerland, Dec. 12, 2024 /PRNewswire/ -- Intensity Therapeutics, Inc. ("Intensity" or "the Company") (Nasdaq: INTS), a late-stage clinical biotechnology company focused on the discovery and development of proprietary, novel immune-based intratumorally injected cancer therapies intended to kill tumors directly and increase immune system recognition of cancers, and The Swiss Group for Clinical Cancer Research SAKK ("SAKK"), a decentralized academic research institute that has been conducting clinical trials of cancer treatments in all major Swiss hospitals since 1965, announced that Andreas Mueller, M.D., Past-President of the Project Group Breast Cancer of SAKK and Head of the Breast Center at Kantonsspital Winterthur, Switzerland and a supporting coordinating investigator for the study presented in an evening poster session on December 11 the final data from Intensity's INVINCIBLE-2 Study (NCT04781725), and an overview / update of the INVINCIBLE-4 Study (NCT06358573) at the San Antonio Breast Cancer Symposium being held December 10-13, at the Henry B. Gonzalez Convention Center in San Antonio, Texas.

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") in the primary tumor and affected lymph nodes. Patients will be randomized one to one to receive a regimen of either two doses of INT230-6 followed by SOC, which consists of pembrolizumab, anthracyclines, carboplatin, cyclophosphamide, and paclitaxel (i.e. the Keynote-522 regimen), or the SOC alone. The study is recruiting and expected to enroll 54 patients.

"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. When the tumor diameters are bigger than two centimeters, recurrence is more likely, so that neoadjuvant treatment is warranted" said Dr. Mueller. "If the immunological cancer cell death caused by INT230-6 and the ignition of an anti-cancer immune response without increased toxicity shows a meaningful increase in pCR, it would be a major advance for the neoadjuvant treatment of breast cancer and potentially other cancers. Further, if the results of this study are highly favorable, perhaps the cardiotoxic anthracycline drugs could be reduced or eliminated in future studies."

The Company's completed INVINCIBLE-2 Study, where INT230-6 was given alone in multiple tumor types including TNBC, showed several benefits:

- Tumor-killing properties at levels greater than 95% in some patients on a single intratumoral dose with systemic immune activation.
- Results in tumors larger than 2 cm showed significant necrosis in 74% of subjects at the time of surgery.
- Gene expression analysis showed a significant difference between baseline biopsies and surgical specimens. Pathway analysis identified genes associated with TCR signaling, B-cell and T-cell activation, with increasing effects in post-treatment samples (SABCS 2023 #PS16-03).
- The study demonstrated pathologic and immune priming effects of intratumoral cytotoxicity in traditional immune quiescent breast cancers, with a treatment that showed favorable safety and was well tolerated.
- INT230-6 patients had significant differential gene expression present and identified genes were associated with T cell activation, lymphocyte activation and inflammatory response.
- INT230-6 patients had increases in CD4 T cells and NK cells within the tumor, and associated changes in the diversity of T cell repertoire.

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 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 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 primary endpoint. For more information about Intensity, including publications, papers, and posters about its novel approach to cancer therapeutics, visit www.intensitytherapeutics.com.

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 overexpression of 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, 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 65%, with rates generally lower in the larger-sized 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 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.

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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