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Intensity Therapeutics, Inc. and The Swiss Group for Clinical Cancer Research SAKK Announce the First Patient Dosed in the Randomized, Presurgical Triple Negative Breast Cancer Phase 2 Clinical Trial (INVINCIBLE-4 / SAKK 66/22)

Testing the efficacy and safety of Intensity's lead drug candidate, INT230-6, when combined with Standard-of-Care versus Standard-of-Care alone

The endpoint is the change in pathological complete response rates

SHELTON, Conn. and BERN, Switzerland, Oct. 31, 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, are collaborating in the INVINCIBLE-4 Study, a Phase 2 trial to treat patients with localized triple-negative breast cancer ("TNBC"), and announce that the first patient has been dosed in the study. The trial (NCT06358573) analyzes INT230-6 given before administration of the standard-of-care neoadjuvant immuno-chemotherapy ("SOC") and the SOC alone by using a 2-cohort design. The study evaluates the pathological complete response ("pCR") rates of the two cohorts relative to a null hypothesis, which is a pCR rate of ≤ 0.6. The success of each cohort in rejecting the null hypotheses will be evaluated.

The Phase 2 study is expected to enroll approximately 54 patients in Switzerland and France. 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 TNBC who undergo SOC treatment and SOC alone. The primary endpoint is 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, or to the SOC alone. The INVINCIBLE-4 Study initiation follows data reported from the Company's INVINCIBLE-2 Study, where INT230-6 given alone showed tumor-killing properties at levels greater than 95% on a single intratumoral dose with systemic immune activation.

"Many TNBC patients undergoing SOC treatment alone fail to achieve a pathological complete response at the time of surgery, especially in larger tumor sizes. INT230-6 has the potential to fill this unmet need for aggressive subtypes, such as TNBC, through its anti-cancer mechanisms of action that cause tumor cell necrosis and ignite an anti-cancer immune-based response," said Andreas Mueller, M.D. Past-President of the Breast Cancer Group at the National Swiss Association for Clinical Cancer Research in Bern Switzerland and Head of Department of Medicine at the Kantonsspital in Winterthur and a supporting coordinating investigator for the study. "The ability for INT230-6 to induce necrosis and activate immune effects before a patient's surgery without increases in toxicity would be a major advance for the treatment of breast cancer and potentially many other cancers."

"The majority of breast cancers are immune quiescent, resulting in minimal response to immunotherapies, and larger tumors are less responsive to therapy," said Ursina Zuerer-Haerdi, MD and Lead Physician for the Department of Medical Oncology and Hematology at the Cantonal Hospital in Winterthur, Switzerland and a supporting coordinating investigator on the study. "We have worked with Intensity to design a study for this novel intratumoral agent with the potential to increase the pathological complete response rates of the current best standard of care that would be clinically meaningful, and this trial is of high interest to SAKK's physician network."

"INT230-6 is an innovative investigational product that combines cisplatin and vinblastine with a penetration enhancer molecule (SHAO)," said Markus Joerger, Prof. MD-PhD and Coordinating Investigator on the study and principal investigator for the Department of Medical Oncology and Hematology at the Cantonal Hospital St. Gallen. INT230-6 results in local immunogenic cell death when injected into the breast tumor, without systemic chemotoxicity but a high potency to induce systemic immunostimulatory effects. INT230-6 tackles the innate immune pathway that is not addressed by immune checkpoint inhibitors, and it is suggested to complement the systemic neoadjuvant backbone in study patients with early-stage TNBC which consists of chemotherapy and the checkpoint inhibitor pembrolizumab. We believe that the SAKK 66/22 study will provide crucial data to inform a large randomized clinical trial in patients with early-stage TNBC, a disease that is still burdened by substantial rates of fatal relapses following potentially curative treatment."

"We are excited to have initiated our Phase 2 study in presurgical triple-negative breast cancer. This study marks the first European patient treated with our drug - a new milestone. Triple-negative is a deadly and aggressive form of breast cancer, and patients having local disease currently undergo a harsh four to six-month regimen whereby a small percentage can die from the SOC before their surgery. Those patients who achieve a pCR have a lower risk of disease recurrence," said Intensity Therapeutics' Founder, Chairman, and CEO, Lewis H. Bender. "We hope that by killing a substantial amount of the tumor upfront and increasing the immune response using INT230-6, we can increase the percentage of patients who achieve pCR and ultimately an improved event-free survival."

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 comprises two proven, potent anti-cancer agents, cisplatin and vinblastine, 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 has been shown to release 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

Approximately 11-17% of breast cancers test negative for estrogen receptors (ER), progesterone receptors (PR), and excess 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, mainly 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 only 63%, with rates generally lower in the larger-sized T2 to T4 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.

About Intensity Therapeutics

Intensity Therapeutics is a late-stage clinical biotechnology company that applies novel engineered chemistry by enabling its aqueous cytotoxic-containing drug product, INT230-6, to mix and saturate the tumor's dense, high-fat pressurized environment. 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 novel approach to cancer cell death that holds the potential to shift the treatment paradigm and turn many deadly cancers into chronic diseases even for cancers that do not respond to

immunotherapy. Intensity complete two large clinical studies using INT230-6 that enrolled over 200 patients: a Phase 1/2 dose escalation trial (NCT03058289) and a Phase 2 randomized control clinical trial in breast cancer (the INVINCIBLE-2 study) (NCT04781725). Intensity Therapeutics 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 with overall survival as an endpoint. The Company is also conducting a Phase 2 study in collaboration with SAKK as part of a Phase 2/3 program evaluating INT230-6 followed by SOC and SOC alone for patients with presurgical triple negative breast cancer. Information on the Phase 2 portion of the program (INVINCIBLE-4 Study) is listed under (NCT06358573). For more information about the Company, including publications, papers and posters about its novel approach to cancer therapeutics, visit www.intensitytherapeutics.com.

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 tothe development of the Company's clinical programs. 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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