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Intensity Therapeutics, Inc. and The Swiss Group for Clinical Cancer Research SAKK Sign a Collaboration Agreement to Conduct a Phase 2 Randomized, Clinical Trial in Early-Stage Breast Cancer in Europe for INT230-6, Intensity's Lead Drug Candidate

SHELTON, Conn., May 10, 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 intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, announces that the Company executed a collaboration agreement with The Swiss Group for Clinical Cancer Research SAKK ("SAKK") to conduct a Phase 2 randomized, (one to one), controlled trial evaluating clinical and biological effects of intratumoral INT230-6 followed by the standard of care ("SOC") immuno/chemotherapy vs. SOC immune/chemotherapy alone in early-stage triple-negative breast cancer ("TNBC") in 54 patients in Switzerland and selected countries in Europe (the "INVINCIBLE-4 Study"). The INVINCIBLE-4 Study is an open-label randomized two-cohort phase 2 clinical trial.

SAKK shall undertake the trial as the "Legal Sponsor" of the study, with the regulatory agencies in Switzerland and the European Union as described in the study protocol. SAKK will also ensure that all investigators and personnel who participate in the study are informed and trained. Intensity shall fund the study, provide the investigational drug product, and other necessary information to conduct the trial. The primary efficacy endpoint of the INVINCIBLE-4 Study is pathological complete response (pCR) in the primary tumor (ypT0/Tis) and affected lymph nodes (ypN0). Additional key research questions include the immune landscape of the tumor microenvironment and peripheral blood, magnetic resonance imaging (MRI) changes predictive for pCR, and adverse events according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v5.0.

"We are excited to be working with SAKK on our INVINCIBLE-4 Study in early-stage triple-

negative breast cancer," said Lewis H. Bender, Founder, President and CEO of Intensity Therapeutics, Inc. "TNBC poses significant challenges due to its aggressiveness, high relapse rates, and increased mortality especially in patients with large tumors. Achieving pathological complete response (pCR) and clearing positive lymph nodes are crucial prognostic factors for event-free survival. Results from our first INVINCBLE-2 study showed that INT230-6 could cause greater than 95% necrosis in large breast cancer tumors following a single dose with the induction of an immune response. By adding up to 2 doses of our unique drug before the standard of care, we hope to increase the rate of patients' pCR, which is an FDA-approved endpoint for accelerated approval. The pCR data from this study, which we expect in the second half of 2025, should provide the information needed to size our Phase 3 trial in presurgical TNBC."

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 composed of 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, direct killing of the tumor by INT230-6 releases a bolus of neoantigens specific to the patient's malignancy, leading to engagement of the immune system and systemic anti-tumor effects. Importantly, these effects are mediated without immunosuppression that so often occurs with systemic chemotherapy.

About Triple Negative Breast Cancer

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.

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 to turn "cold" tumors "hot" by enabling its aqueous cytotoxic-containing drug product, INT230-6, to mix and saturate the dense, high-fat pressurized environment of the tumor. 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. INT230-6 has completed enrollment of over 200 patients in a Phase 1/2 dose escalation trial (NCT03058289) and Phase 2 randomized control clinical trial in breast cancer (the INVINCIBLE 2 study) (NCT04781725). The Company is initiating 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 planning a Phase 2/3 program in presurgical triple-negative breast cancer testing INT230-6 in combination with standard of care compared to standard of care alone. 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 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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