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Drug Monitoring Committee Authorizes Continuation of Intensity Therapeutics' Ongoing Global Randomized Phase 3 Sarcoma Trial ("INVINCIBLE-3 Study") Following Periodic Review

INVINCIBLE-3 Study continues to recruit patients with leiomyosarcoma, liposarcoma and undifferentiated pleomorphic sarcoma; authorizations for the INVINCIBLE-3 Study have been received in the U.S., Canada, Europe and Australia

SHELTON, Conn., Jan. 28, 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 that following its most recent periodic review meeting, the Data Monitoring Committee (DMC) overseeing the Company's ongoing Phase 3 sarcoma study of INT230-6 (INVINCIBLE-3) (NCT06263231) has agreed that the study should continue without modification. The DMC reviewed data covering the six months from July to December 2024.

"The Data Monitoring Committee is designed to confidentially review data to determine whether safety concerns with the data collected to date exist. We are encouraged by the continuation of the trial and continue to believe that INT230-6 represents important potential in a treatment area that has significantly unmet medical need. We look forward to continuing enrollment and to providing further updates as they develop," commented Lewis H. Bender, Intensity's President and Chief Executive Officer.

INVINCIBLE-3 Study Overview

The INVINCIBLE-3 Study is a global open-label, randomized, controlled study designed to evaluate INT230-6 administered intratumorally by an interventional radiologist or an equivalently trained physician using image guidance compared to systemically dosed standard of care ("SOC") chemotherapy. The study endpoints are overall survival and safety, along with an exploratory quality of life (QoL) assessment using the EORTC-30 survey. The study is testing the efficacy and safety of INT230-6 intratumoral (IT) injection compared to any of three standard-of-care therapies (pazopanib, trabectedin, or eribulin) in

approximately 333 adult participants with locally recurrent, inoperable, or metastatic soft tissue sarcoma ("STS") patients who had disease progression prior to study enrollment following standard therapies, which must have included an anthracycline-based regimen unless contraindicated. Participants may also have received a maximum of one additional regimen. Randomization will occur after screening and eligibility confirmation. As this is a survival study, there is no crossover allowed between SOC and INT230-6. Disease progression will be determined by the World Health Organization (WHO) criteria. Participants will be prospectively stratified into 1 of 3 histologically defined STS strata:

- leiomyosarcoma
- liposarcoma (dedifferentiated, myxoid, round cell and pleomorphic)
- undifferentiated pleomorphic sarcoma

The comparator agents used are all U.S., Europe, Canadian and Australian-approved agents for sarcomas: pazopanib tablets, trabectedin, and eribulin mesylate. Authorizations for the INVINCIBLE-3 Study have been obtained from the U.S. FDA, Health Canada, the European Medicines Agency, and Australia's Therapeutic Goods Administration. Sites will be opened in 8 countries and the study is presently recruiting participants in the U.S., Canada, and Europe.

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 endpoint. For more information about Intensity, 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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