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Intensity Therapeutics, Inc. Announces that INT230-6 Achieved 100% Complete Response Rate in Preclinical Models of Malignant Peripheral Nerve Sheath Tumors (MPNST)

SHELTON, Conn., June 30, 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 INT230-6 achieved complete responses in a murine models of Malignant Peripheral Nerve Sheath Tumor ("MPNST"). In a study conducted in the Staedtke-Bai laboratory at Johns Hopkins University, at 21 days, animals tested with INT230-6 (n=5) all achieved a complete response, whereas all animals' tumors in the control group (N=5) continued to grow.



"We are excited to see complete responses in a murine model of malignant peripheral nerve sheath tumors, an effect that no small molecule drug before INT230-6 has achieved in our lab before," said Renyuan Bai, PhD, Kennedy Krieger Institute, Associate Professor, Department of Neurosurgery and Oncology Center, Johns Hopkins University School of Medicine, and the coordinating scientist for the study. "We are encouraged that these results can be achieved in this difficult-to-treat neurological model and look forward to continuing to work with Intensity on other preclinical models of neurological tumors."

"MPNST is the first neurological-specific tumor for which INT230-6 has been used. We are pleased to see that INT230-6 achieved meaningful results in MPMNST that are similar to the results we saw in other *in vivo* models where INT230-6 has been tested," said Lewis H. Bender, President and CEO of Intensity. "We look forward to conducting further preclinical research with the Staedtke-Bai laboratory in other neurological cancer models."

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 DfuseRxSM technology platform. The drug consists of two proven, potent anti-cancer agents, cisplatin

and vinblastine sulfate, and a diffusion and cell penetration enhancer molecule ("SHAO") that facilitates the dispersion of potent cytotoxic drugs throughout tumors, allowing the active agents to diffuse 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 Malignant Peripheral Nerve Sheath Tumor

Malignant peripheral nerve sheath tumor (MPNST) is a rare and aggressive type of sarcoma that originates from the peripheral nerves or their surrounding sheath. Few therapies have been proven effective despite extensive efforts, and the five-year survival is 20 to 50%. Current treatment involves surgery, chemotherapy and radiation. The disease is characterized by its tendency to recur after treatment and metastasize to distant sites, making it a challenging cancer to manage. MPNSTs can arise spontaneously or are associated with neurofibromatosis type 1, referred to as NF1. They develop from the cells of the peripheral nerve sheath. One in 3,000 people can carry *NF1* gene alternations and are predisposed to tumor formation, which can occur anywhere in the body. MPNSTs are most commonly found in the extremities and trunk. Common sites include the sciatic nerve, brachial plexus, and sacral plexus.

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 the Staedtke-Bai Laboratory

The Staedtke-Bai laboratory, also known as the Staedtke-Bai Living Therapeutics Laboratory, is a research group at Johns Hopkins that focuses on neurofibromatosis and related nervous system cancers. Led by Dr. Verena Staedtke, who passed away recently, and Dr. Renyuan Bai, the lab investigates mechanisms of immune-mediated toxicity and

anti-tumor responses following immunotherapy, with a specific interest in brain cancer immunotherapy.

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 risk that product candidates that appear promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later clinical trials; 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; our potential inability to satisfy the Nasdaq Capital Market's requirements for continued listing and be subject to delisting; 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 Annual Report on Form 10-K for the year ended December 31, 2024 and in the Company's subsequent 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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