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Intensity Therapeutics Receives Orphan Drug Designation for the three key ingredients in INT230-6 for the Treatment of Soft Tissue Sarcoma

WESTPORT, Conn., Sept. 7, 2023 /PRNewswire/ -- Intensity Therapeutics, Inc. ("Intensity" or the "Company") (Nasdaq: INTS), a clinical-stage 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, today announced that the US Food and Drug Administration's Office of Orphan Products Development has granted orphan-drug designation for the treatment of soft tissue sarcoma (STS) to the three active moieties comprising INT230-6, cisplatin, vinblastine sulfate, and the diffusion enhancer SHAO-FA (8-((2-hydroxybenzoyl) amino)octanoate). INT230-6 is the Company's lead product candidate.

"The designation of cisplatin, vinblastine and our diffusion enhancer, SHAO for orphan status for STS is quite important," said Lewis H. Bender President and CEO. "The Orphan Drug Designation qualifies us for incentives including tax credits for qualified clinical trials, exemption from user fees and potentially seven years of marketing exclusivity for products containing these three key components should the Company gain approval of INT230-6 for treatment of STS."

An FDA condition to obtain orphan drug designation was for the Company to provide a scientific rationale in its application with sufficient data to establish a medically plausible basis for expecting the drug to be effective in STS. The Company submitted clinical data including immune activation results in sarcoma patients.

At ASCO in June 2023 Assistant Professor of Oncology at the Sidney Kimmel Cancer Center at Johns Hopkins University Christian Frederick Meyer, M.D., Ph.D., M.S., an investigator involved in Intensity's Phase 1/2 clinical study, reported that compared to synthetic controls, median overall survival using INT230-6 alone in refractory soft tissue sarcoma subjects was prolonged by nearly 450 days with favorable safety over what would have been expected for the patient population. Data also reported at ASCO showed that INT230-6 when delivered locally led to a systemic immune response in several sarcoma subtypes that are considered to be non-immunogenic cancers. Intensity is planning a phase

3 registration study in STS.

About Soft Tissue Sarcoma
Soft tissue sarcoma is a broad term for cancers that start in soft tissues (muscle, tendons, fat, lymph and blood vessels, and nerves). These cancers can develop anywhere in the body but are found mostly in the arms, legs, chest, and abdomen. There are many types of sarcoma; however, the four most common are bone sarcoma (referred to as osteosarcoma), leiomyosarcoma, undifferentiated pleomorphic sarcoma (UPS) and liposarcoma. When sarcoma is metastatic prognosis is poor; even with chemotherapy, half of people diagnosed with metastatic disease die within 15 months. Each year, 12,000 people in the U.S. and 1,150 in Canada are diagnosed with soft tissue sarcomas. About 3,000 patients have bone sarcomas.

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.

About Intensity Therapeutics
Intensity Therapeutics, Inc. is a clinical-stage biotechnology company pioneering a new immune-based approach to treat solid tumor cancers. Intensity leverages its DfuseRx℠ technology platform to create proprietary drug formulations that following direct injection rapidly disperse throughout a tumor and diffuse therapeutic agents into cancer cells. Intensity's product candidates have the potential to induce an adaptive immune response that not only attacks the injected tumor, but also non-injected tumors. The Company's lead product candidate, INT230-6, is in development for the treatment of patients with solid tumors, such as sarcoma and breast cancer. Intensity has a clinical collaboration agreement with Merck Sharpe & Dohme (Merck) to evaluate INT230-6 with pembrolizumab. In addition, the Company has a clinical collaboration agreement with Bristol-Myers Squibb to evaluate INT230-6 with Bristol-Myers Squibb's anti-CTLA-4 antibody, ipilimumab. Intensity has also executed agreements with the Ottawa Hospital Research Institute (OHRI) and the Ontario Institute of Cancer Research (OICR) to study INT230-6 in a randomized controlled neoadjuvant phase 2 study in women with early stage breast cancer (the INVINCIBLE study) (NCT04781725). Additionally, the Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch. For more information, please visit www.intensitytherapeutics.com and follow the Company on Twitter @IntensityInc.

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 expected future plans, development activities, projected milestones, business activities or results. We have based these forward-looking statements on our 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 we make. These risks and uncertainties, many of which are beyond our control, include: the risk that the anticipated milestones may be delayed or not occur or be changed, as well as 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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