July 9, 2024

Intensity Therapeutics, Inc. Announces First Patient Dosed in its Global Randomized, Phase 3 Study (INVINCIBLE-3) in Metastatic Soft Tissue Sarcoma

Testing the efficacy and safety of our lead product candidate, INT230-6, as Monotherapy Compared with Systemic U.S. Standard-of-Care Chemotherapy

SHELTON, Conn., July 9, 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, announces that the first U.S. patient has been dosed in the Company's Phase 3 study to treat metastatic sarcoma (NCT06263231). The trial is a superiority study testing INT230-6 as monotherapy compared to the investigator's choice of three current standard-of-care systemic chemotherapy drugs in second or third-line metastatic, recurrent, or inoperable soft tissue sarcomas ("STS").

The global Phase 3 study is expected to enroll approximately 333 patients. The primary endpoint is overall survival. For every three patients treated, two will receive INT230-6, and one will receive the standard of care. STS subtypes being enrolled are leiomyosarcoma, liposarcoma, and undifferentiated pleomorphic sarcoma. The Phase 3 initiation follows reported data from the Company's Phase 1/2 trial, where INT230-6 showed tumor-killing and immune-activating properties with increased survival in metastatic disease.

"We have now dosed our first patient in the U.S. and have filed regulatory documents to initiate this trial in Canada and Europe. Over the next several months, we anticipate initiating sites in eight countries. Sarcoma is a deadly cancer with a median overall survival following second and third-line drug treatments of between 10 and 15 months," said Intensity Therapeutics' Founder, Chairman, and CEO, Lewis H. Bender. "During our phase 1/2 metastatic dose escalation study, in a sarcoma population that had progressed following a median of 3 lines of therapy, we reported a median overall survival of 21.3 months with our drug alone. Patients, their caregivers, and physicians worldwide desperately need improved treatment options and we are excited to have finally begun testing our new approach in Phase 3. I want to take this opportunity to thank our dedicated team for getting us to this

tremendous milestone."

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 killing of the tumor, INT230-6 releases 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 Sarcoma

Soft tissue sarcoma is a rare type of cancer that starts with the growth of cells in the body's soft tissue, such as muscle, fat, blood vessels, nerves, tendons, and linings of the joints. The disease mostly occurs in the arms, legs and belly. There are 197,000 patients in the US living with sarcoma and more than 50 types of soft tissue sarcoma, the treatment of which first involves surgery. Other treatments might include radiation therapy and then chemotherapy. Using the U.S. SEER database, the Company estimated that 14,337 patients have regional or distal (metastatic) leiomyosarcoma, liposarcoma, and undifferentiated pleomorphic sarcoma.

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 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 even for cancers that do not respond to immunotherapy. INT230-6 has completed enrollment of over 200 patients in two studies; a Phase 1/2 dose escalation trial (NCT03058289), and a Phase 2 randomized control clinical trial in breast cancer (the INVINCIBLE 2 study) (NCT04781725). The Company recently 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 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. Information on the Phase 2, (INVINCIBLE-4-SAKK 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 to the 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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