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Intensity Therapeutics Presents INT230-6 Phase 1/2 Data in Sarcoma and an Overview of its Ongoing Global Randomized Phase 3 Sarcoma Trial ("INVINCIBLE-3 Study") in a Late-Breaking Session at the 2024 Annual Connective Tissue Oncology Society Meeting (CTOS)

Phase 1/2 data showed a median overall survival ("mOS") of 21.3 months versus a synthetic control of 6.7 months, an increase in T-cell activation, and favorable safety profile for patients receiving INT230-6 alone

INVINCIBLE-3 Study is recruiting and expected to enroll 333 patients with leiomyosarcoma, liposarcoma and undeferential pleomorphic sarcoma; authorizations for the INVINCIBLE-3 Study have been received in the U.S., Canada, Europe and Australia

SHELTON, Conn., Nov. 18, 2024 /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, today announced that Christian F. Meyer M.D., Ph.D., Assistant Professor of Oncology and lead medical oncologist for adult sarcoma patients at Johns Hopkins University's Sidney Kimmel Cancer Center, presented final safety and efficacy data from the Company's Phase 1/2 clinical trial of INT230-6 that was used as a monotherapy in patients with relapsed, refractory, and metastatic sarcomas, along with an overview of the Company's ongoing INVINCIBLE-3 Study design (NCT06263231). Dr. Meyer shared the information during an oral podium presentation in a late-breaking session at the 2024 Connective Tissue Oncology Society ("CTOS") on November 16, 2024, at 9 AM PST. The abstract's lead author was Albiruni Razak, MB BCh, BM BCh, Clinician Investigator, Princess Margaret Cancer Centre at the University Hospital Network in Toronto, Ontario, Canada. Both Drs. Razak and Meyer, enrolled patients in the Phase 1/2 clinical trial. This year's annual CTOS conference was held in San Diego from November 13 to 16, 2024 at the Grand Hyatt.

"The data in the Phase 1/2 study has shown that INT230-6 causes cell death leading to tumor necrosis, improved cancer recognition by immune cells, and an ignition of a systemic anti-cancer immune response that results in T-cells entering the tumor microenvironment and has shown a favorable safety profile in soft tissue sarcomas," said Dr. Razak. "Systemically delivered chemotherapies have severe side effects, including cardiotoxicity, and most sarcoma subtypes have only a minimal response to immunotherapies. In addition, most sarcoma patients remain on current therapies for only a few months prior to progression, death or excessive toxicity. Demonstrating statistically significant improvement in median overall survival for the INT230-6 treatment arm compared to the standard of care arm in the INVINCIBLE-3 Study would be a major step forward in treating patients with these deadly soft tissue sarcomas."

Phase 1/2 Study (Sarcoma Subset Data: 15 Patients):

Demographics:

- Median (min, max) lines for prior drug therapies: 3 (1.00, 7.00)
- Mean (SD) age: 62.8 (8.1) years and ranged from 41.9 to 76.1 years
- ECOG performance status at screening was 0, 1 and 2 for 2 (13.3%), 12 (80.0%), and 1 (6.7%) subjects respectively
- The sarcoma diagnoses of the Phase 2 patients included liposarcoma, pleomorphic sarcoma, leiomyosarcoma, chondrosarcoma, osteosarcoma (chondroid syringoma), myofibroblastic, osteosarcoma, Kaposi sarcoma and chordoma

Efficacy:

- The mOS in the mixed sarcoma population: 21.3 months for INT230-6
- The mOS had not been reached with 21.4 months of median follow-up for patients who received a cumulative INT230-6 dose volume that was greater than 40% of their total tumor burden
- INT230-6 extended overall survival in refractory sarcoma subjects by nearly 15 months as monotherapy when compared to a synthetic control group based on the Royal Marsden Hospital scoring method
- Sarcoma population's overall disease control rate (DCR): 93.3% (95% CI: 68.1, 99.8) at 2 months
- Median duration of response (DOR): 4.0 months (95% CI: 1.7, NA) and 11.3 months (95% CI: 2.8, NA) for subjects who received a cumulative dose of ≥ 40% of the total incoming total tumor burden
- INT230-6 demonstrated an increase in T-cells within the tumors
- 27% of patients had uninjected tumors shrink (abscopal effects), though tumors less than 1 cm were uninjected, untracked and unreported by investigators, so the true abscopal percentage is unknown; further radiomics work is on-going

Safety

- INT230-6 demonstrated a favorable safety profile and was well-tolerated
- 3 subjects (20%) had one or more drug regimen-related Grade ≥ 3 Treatment Emergent Adverse Events (TEAE); all were grade 3 (there were no grade 4 or 5 TEAEs)

INVINCIBLE-3 Study Overview
The INVINCIBLE-3 Study is 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. This is a global randomized Phase 3 study comparing the efficacy and safety of INT230-6 intratumoral (IT) injection with 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.

"The safety and efficacy data of our lead drug candidate, INT230-6, generated for sarcomas was quite encouraging. Many insights were gained from the over 200 patients treated before initiating the INVINCIBLE-3 study and applied to the ongoing study. Our approach uses sophisticated interventional radiology technologies to guide needles into tumors to inject our novel cytotoxic drug, which is highly absorbed by tumors, and showed a potential meaningful impact on lengthening metastatic sarcoma patient lives, reducing toxicities and improving quality of life compared to current treatments in our first clinical trial," said Lewis H. Bender, Intensity's President and Chief Executive Officer. "Our unique chemistry enables water-based products to diffuse throughout tumors and into cancer cells, causing immunologic cell death."

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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