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Intensity Therapeutics Reports Use of INT230-6 Alone or in Combination with Ipilimumab Shows Evidence of Direct Tumor Necrosis and Promising Overall Survival Results in Adult Subjects with Metastatic Sarcomas at the Connective Tissue Oncology Society (CTOS) 2021 Virtual Annual Meeting

Data from Ongoing Phase 1/2 Study of INT230-6 Alone or in Combination with Ipilimumab (INTENSITY# IT-01; BMS# CA184-592) Selected for Oral Podium Presentation

Exploratory Kaplan Meier Analysis of a Sarcoma Population that Failed a Median of 3 Prior Therapies Estimates that 60% of Subjects were Alive at 1 Year When Treated with INT230-6 (Alone and with Checkpoints) at a Dose Greater than 40% of their Incoming Total Tumor Burden

WESTPORT, Conn., Nov. 12, 2021 /PRNewswire/ --**Intensity Therapeutics, Inc.** ("Intensity"), a clinical-stage biotechnology company focused on the discovery and development of proprietary immune-based intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, today announced that data from its open-label Phase 1/2 study of novel lead asset, INT230-6, as a monotherapy or in combination with ipilimumab in adult subjects with metastatic sarcomas, is being presented today, in an oral presentation, at the Connective Tissue Oncology Society Virtual Annual Meeting (CTOS).

"Preliminary data suggests that INT230-6, as a monotherapy, demonstrates direct tumor killing in soft tissue sarcoma subjects (STS) and elicits an anti-cancer immune response within the injected tumor," stated poster presenter and study investigator, Matthew A. Ingham, MD, Assistant Professor of Medicine in the Division of Hematology and Oncology at Columbia University Vagelos College of Physicians and Surgeons and first author of the study. "To date, though in a limited number of patients, INT230-6 treatment related adverse events are mostly low grade and the drug is well-tolerated either as a monotherapy or in combination with checkpoint inhibitor, ipilimumab. Additionally, an exploratory analysis showed an increase in survival with dosing a volume of INT230-6 above forty percent of the

total tumor burden, as compared to survival from historical sarcoma studies. These results provide further evidence to continue studying this novel therapeutic drug approach."

Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics, added, "The promising data supports our belief that INT230-6, a locally-delivered anti-cancer product candidate, may potentially lead to clinical benefit with lower levels of off target side effects compared to chemotherapies for patients with advanced soft tissue sarcomas. Given these results, earlier this year we met with and reached alignment with FDA of the design of a randomized Phase 3 trial, subject to review by the Agency of the final protocol, to evaluate INT230-6 versus standard of care in patients with advanced soft tissue sarcomas."

Title: *Safety and Efficacy from a Phase 1/2 Study of Intratumoral INT230-6 Alone or In Combination with Ipilimumab [INTENSITY# IT-01; BMS# CA184-592] in Adult Subjects with Metastatic Sarcomas (NCT 03058289)*

The presentation will be accessible on the "Publications, Papers and Posters" section of Intensity's website at: https://intensitytherapeutics.com/news/publications-papers-and-posters/.

The data presented included results from 19 patients with different metastatic sarcomas treated with INT230-6 either as a monotherapy (n=10), or in combination with a checkpoint inhibitor (n=8) primarily ipilimumab. The enrolled patients' cancer progressed following a median of three prior lines of therapy (range 0 to 9) including all approved, appropriate therapies for a subject's particular cancer. Demographics were similar in subjects enrolled in monotherapy and checkpoint inhibitor combination arms. The cumulative dose of INT230-6 IT injections ranged from 20 to 530mL (265mg cisplatin, 53mg vinblastine), with repeated intratumoral injections in multiple tumors. Pharmacokinetic (PK) profile analysis from 18 STS subjects in study IT-01 were analyzed for cisplatin, SHAO and vinblastine and show less than 5% of the drugs enter the blood stream.

A retrospective exploratory analysis of subjects was assessed by comparing INT230-6 dosed at greater than or equal to 40% of their incoming total tumor burden, suggesting promising survival. For sarcoma subjects dosed to >40% of their total tumor burden, approximately 60% of subjects will be alive at 1 year. These results compare favorably to those seen in historical Phase 1/2 studies of sarcoma subjects where approximately 50% of subjects are deceased at 3 to 8 months depending on certain prognostic factors (ECOG, LDH, # of metastatic sites). Abscopal effects were seen in visceral lesions in two subjects, which may be an underestimation, as no tumors under 1 cm and not all larger lesions were followed.

Immunohistochemistry analysis of INT230-6 monotherapy paired (pre- and 28 days post-dose) biopsy of injected lesions from 3 INT230-6 monotherapy STS subjects showed a median of 60% reduction in tumor cell content and a 72% reduction in Ki67 staining (proliferation marker).

Hematoxylin and Eosin assessments demonstrated substantial reductions of cancer cells in biopsies from monotherapy subjects after two injections of INT230-6 when compared to baseline. Local delivery of INT230-6 as monotherapy into tumors induced an immune response with increases of activated CD4+ and CD8+ T-cells in the tumor with a few low grade immune-related adverse events. These clinical results are consistent with immune

findings from in vivo models. Most other adverse events were low grade and transient, consisting mostly of pain at the injection site (68.4% of patients), fatigue (42.1%) or decreased appetite (36%). There were no grade 4 or 5 treatment emergent adverse events and no events that were dose limiting.

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 that helps disperse the drugs throughout tumors for diffusion into cancer cells. In addition to local disease control, direct killing of the tumor by INT230-6 creates neoantigens leading to engagement of the immune system and systemic anti-tumor effects in the tumor. Importantly, these effects are mediated without the immunosuppression of concomitant systemic chemotherapy.

INT230-6 is currently being evaluated in several Phase 2 cohorts NCT03058289) in patients with various advanced solid tumors as part of Study IT-01. In 2019, the Company signed a clinical collaboration agreement with Merck Sharpe & Dohme (Merck) to evaluate the combination of INT230-6 and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced pancreatic, colon, squamous cell and bile duct malignancies. In 2020, the Company executed a clinical collaboration agreement with Bristol-Myers Squibb Company to evaluate the combination of INT230-6 with Bristol-Myers Squibb's anti-CTLA-4 antibody, Yervoy® (ipilimumab), in patients with advanced liver, breast and sarcoma cancers. In 2021, the Company executed agreements with the Ottawa Hospital Research Institute and the Ontario Institute of Cancer Research to study INT230-6 in a randomized controlled neoadjuvant Phase 2 study in women with early stage breast cancer (the INVINCIBLE study) (NCT04781725).

About Intensity Therapeutics

Intensity Therapeutics, Inc. is a privately held, clinical-stage biotechnology company pioneering a new immune-based approach to treat solid tumor cancers. Intensity leverages its DfuseRx℠ technology platform to create new, 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 systemic immune response that not only attacks the injected tumor, but also non-injected tumors. The Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch in 2014 and has partnerships with Merck and Bristol-Myers Squibb. For more information, please visit www.intensitytherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements regarding Intensity Therapeutics' plans, future operations and objectives. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual performance or achievements to be materially different from those currently anticipated. These forward-looking statements include, among other things, statements about the initiation and timing of future clinical trials.

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