

November 18, 2022



# **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) 2022**

*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 the refractory Sarcoma Population Shows that dosing INT230-6 Equivalent to 40% or More of the Patient's Tumor Burden During the Course of Therapy Results in a Median Overall Survival of 715 Days Compared to a mOS of 205 days or a Historical Refractory Sarcoma Control*

WESTPORT, Conn., Nov. 18, 2022 /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, will be presented today in an oral podium presentation, at the Connective Tissue Oncology Society Annual Meeting (CTOS) being held at the Vancouver Convention Center in Vancouver, BC, Canada from November 16 -19, 2022.

"Preliminary data suggests that INT230-6, as a monotherapy or in combination with the immune checkpoint blocker ipilimumab, demonstrates direct tumor killing in soft tissue sarcoma (STS) and elicits an anti-cancer immune response within the injected tumor," stated [Matthew Ingham](#), M.D., assistant professor of medicine in the Division of Hematology and Oncology, Columbia University Vagelos College of Physicians and Surgeons, and a principal investigator for the trial. "To date, INT230-6 treatment related adverse events are mostly low grade and the drug is well-tolerated either as a monotherapy or in combination with ipilimumab. Additionally, in patients who had 40% or more of their tumor burden treated with INT230-6, an exploratory analysis showed that overall survival was improved when compared to historical benchmarks for this patient population."

[Lewis H. Bender](#), President and Chief Executive Officer of Intensity Therapeutics, added, "The compelling safety and efficacy results from use of our drug in treating such a deadly

and hard-to-treat cancer as soft tissue sarcomas underscore the potential of this treatment. The promising data supports our belief that INT230-6 could show clinical benefit with lower levels of off-target side effects compared to standard chemotherapies. We have designed a randomized phase 3 trial protocol to evaluate INT230-6 versus standard of care in patients with advanced soft tissue sarcomas and look forward to initiation of the study."

**Abstract ID:** 1301741

**Title:** *Intratumoral INT230-6 (Cisplatin, Vinblastine, Shao) Alone or with Ipilimumab Prolonged Survival with Favorable Safety in Adults with Refractory Sarcomas*  
([NCT03058289](https://clinicaltrials.gov/ct2/show/study/NCT03058289))

**Session:** Session 9: Immunology & Immunotherapy

**Session Date** Friday, November 18, 2022

**Time:** 3:30 PM - 5:00 PM PST

**First Author:** Matthew Ingham, M.D.

**Presenter:** Christian Meyer, M.D.

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 29 patients with different metastatic sarcomas treated with INT230-6 either as a monotherapy (n=15), or in combination with ipilimumab (n=14). 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. Pharmacokinetic data shows that >95% of the active agents remain in the tumor. Immunohistochemistry shows that there is an increase in the immune cell infiltration pre and post dose.

Study IT-01 is a single arm study; however, published clinical phase 1/2 basket trials in sarcoma report mOS, ranging from 230 to 290 days (Jones et. al., Cassier et. al., Subbiah et. al.). Using the Subbiah study data a synthetic control group Kaplan Meier (KM) survival curve was generated. The overall survival of the control, all INT230-6 patients and those receiving a cumulative dose of greater than 40% of their total tumor burden (TTB), are shown in the below table. Subjects receiving combination with ipilimumab have not yet reached median survival with 345 days median follow-up. There have been only 2 deaths reported in the combination group as of data cut-off. Sarcoma subtypes may differ between groups and data is still early.

Sarcoma phase 1/2 studies	Control (Subbiah)	INT230-6 all	INT230-6 >40% TTB	INT230-6 + IPI
Median OS	205 days	649 days	715 days	Not yet reached*
Confidence Interval	-	(195, 1352)	(649, 1352)	
Sample size	56	15	11	14

## 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<sup>SM</sup> 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. 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, 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 clinical-stage biotechnology company pioneering a new immune-based approach to treat solid tumor cancers. Intensity leverages its DfuseRx<sup>SM</sup> 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 cause tumor necrosis and induce an adaptive immune response that not only attacks the injected tumor, but also non-injected tumors. In addition to partnerships with Merck and Bristol-Myers Squibb, the Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch in 2014. For more information, please visit [www.intensitytherapeutics.com](http://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 trading commencement and closing dates. 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 initial public offering of common stock may not close, as well as other risks described in the section entitled "Risk Factors" in the prospectus, which can be obtained on the SEC website at [www.sec.gov](http://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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