UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 5, 2023

Intensity Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-41109	46-1488089
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1 Enterprise Drive, Suite 430 Shelton, CT	06484-4779
(Address of Principal Executive Offices)	(Zip Code)

(203) 221-7381
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading Symbol(s):	Name of Exchange on Which Registered:
Common Stock, $0.0001 par value per share	INTS	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 7.01 Regulation FD Disclosure.

On September 5, 2023, Intensity Therapeutics, Inc. (the "Company") announced via press release that it will present a corporate presentation at the H.C. Wainwright 25th Annual Global Investment Conference on Monday, September 11, 2023. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K. A copy of the corporate presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K.

The information contained in Item 7.01 in this Current Report on Form 8-K and Exhibits 99.1 and 99.2 attached hereto are intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated September 5, 2023.
99.2	Corporate Presentation of Intensity Therapeutics, Inc., dated September 11, 2023.
104	Cover Page Interactive Data File (formatted in Inline XBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 5, 2023

Intensity Therapeutics, Inc.

By: /s/ Lewis H. Bender
Name: Lewis H. Bender
Title: Chief Executive Officer

[*Signature Page to the Form 8-K*]

Exhibit 99.1

Intensity Therapeutics to Present at the H.C. Wainwright 25th Annual Global Investment Conference

WESTPORT, Conn., September 5, 2023 – Intensity Therapeutics, Inc. (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 Lewis H. Bender, President and Chief Executive Officer, will present a company overview at the H.C. Wainwright 25th Annual Global Investment Conference on Monday, September 11, at 4:30 pm ET.

Mr. Bender will also host in-person and virtual one-on-one meetings during the event. Institutional investors who are registered for the conference can log into www.hcwevents.com to request a meeting with the company.

A live webcast of the presentation can be accessed here and will be available on the Intensity Therapeutics website at: https://ir.intensitytherapeutics.com/news-events/events-presentations. An archived replay will be available on the company's website for approximately 90 days following the conclusion of the conference.

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 the combination 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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Issuer Free Writing Prospectus Filed
pursuant to Rule 433 Registration
Number 333-260565

Intensity THERAPEUTICS

A New Weapon in the War on Cancer

September 2023

Highlights

- Novel cancer treatment approach with first-in-class compound that causes cancer cell death leading to an immune response for indications with high unmet medical need
- Late-stage pipeline programs in metastatic and presurgical settings with multiple near-term inflexion points
- Experienced leadership team from Emisphere, Roche and Bristol Myers; CEO has public company as well as biopharma development and commercial experience
- Robust IP portfolio, platform validated through multiple Industry, government and university hospital partnerships
- De-risked and cost-efficient business model structured to create significant value

Platform Validated by World Leading Partners

Intensity Therapeutics

RESEARCH

NIH National Cancer Institute

OICR Ontario Institute for Cancer Research

Merck

KEYTRUDA® (pembrolizumab) Injection 100 mg

Bristol Myers Squibb™

YERVOY™ (ipilimumab)

CLINICAL TRIAL SITES

Johns Hopkins Medicine – The Sidney Kimmel Comprehensive Cancer Center

Keck Medical Center of USC – Keck Medicine of USC

Fox Chase Cancer Center – Temple Health

Columbia – Columbia University Herbert Irving Comprehensive Cancer Center

UMassMemorial

UHN Princess Margaret Cancer Centre

Houston Methodist – Leading Medicine

The Ottawa Hospital Research Institute | L'Hôpital d'Ottawa Institut de recherche

Management Team:

Extensive Oncology and Drug Development Experience

Veteran Operators with Public Company and IPO Experience

Intensity Therapeutics

Lewis H. Bender, *MIT ChE, MS, MA, MBA*
Founder, CEO

- Drug delivery expertise Preclinical through Phase 3
- Public biotech company CEO experience

Emisphere – CEO, CTO, VP, BD & Manufacturing

Roche – Manufacturing

Interleukin Genetics – CEO

James M. Ahlers
Executive Vice President – Corporate Finance

- 25 years, multiple transactions
- Titan Pharmaceutics, IPO

Danforth Advisors

Intarcia

Brian Schwartz, MD
Clinical Development

LifeSci Advisors

Ziopharm Oncology

ArQule

Mereo BioPharma

John Wesolowski, *MBA, CPA*
Chief Financial Officer, Principal Accounting Officer and Controller

Yale

KMG

KEY MANAGEMENT

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Bristol Myers Squibb

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Lewis H. Bender
CEO Intensity

Emisphere

Multiple Late-Stage Pipeline Programs
Clinical Programs Across Metastatic and Presurgical Settings

Phase 2 Studies finishing; Phase 3 Programs Designed, Discussed with FDA and in process of initiating

CLINICAL

INT230-6	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	
Advanced Soft Tissue Sarcoma			INT230-6 randomized Phase 3 Protocol drafted, CRO engaged		Phase 3 start potential H124
Neoadjuvant Breast Cancer			INT230-6 randomized Phase 2/3 designed		Phase 2/3 start potential H124
Early-Stage Breast Cancer on-going			The INVICIBLE Study: INT230-6 pre-surgical local or regional disease		#Randomized Controlled: data expected Q4 2023
Colorectal, Bile Duct, Pancreatic Squamous cell cancers (on-going)			Combo with Merck's Keytruda® (non-immunogenic "cold tumors")		#Final Data expected 2023
Sarcoma, Breast, Hepatic Cancers (on-going)			Combo with + BMS' Yervoy®		#Final Data expected 2023
INT230-6 TNBC* (Metastatic)			Randomized Controlled		*Phase 2/3 study per fast track

*TNBC is triple negative breast cancer

#Enrollment completed

First Two Clinical Market Opportunities

- **Phase 3 programs - important market opportunities:**

Metastatic sarcoma:

- 157,000 patients in US;
- 12,000 new cases per year (6,000 deaths); (US)
- *Estimated annual revenue per patient based on phase 2 use*

Breast Cancer

- ~287,850 new cases of invasive breast cancer diagnosed in women in the U.S. during 2022
- About 1 in 8 U.S. women (about 13%) will develop invasive breast cancer over the course of her lifetime

Presurgical breast cancer:

- INT230-6 with Standard of Care (SOC) chemotherapy: 30,000 patients US
- w/out chemotherapy: 60,000 Large tumor cases; (US) INT230-6 vs. no treatment (current SOC)

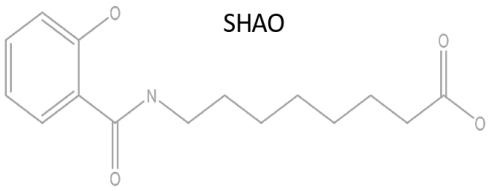
Proprietary Discovery Platform - DFUSERx[SM] Created INT230-6

- **Designed for intratumoral (IT) use in the fatty environment of a tumor;**
  Drug is 100% water-based, scaled-up, stable, & reproducible

- **Product Candidate: INT230-6 – Uses two proven, commercial anti-cancer agents**
  Cisplatin and Vinblastine Sulfate; both drugs **kill cancer directly**
  And via different mechanisms **cause anti-cancer immune activation**

- **Novel diffusion enhancer (SHAO)**

SHAO



- Enables the drugs to become soluble in fat and water
- Disperses throughout the tumor and diffuse into cancer cells

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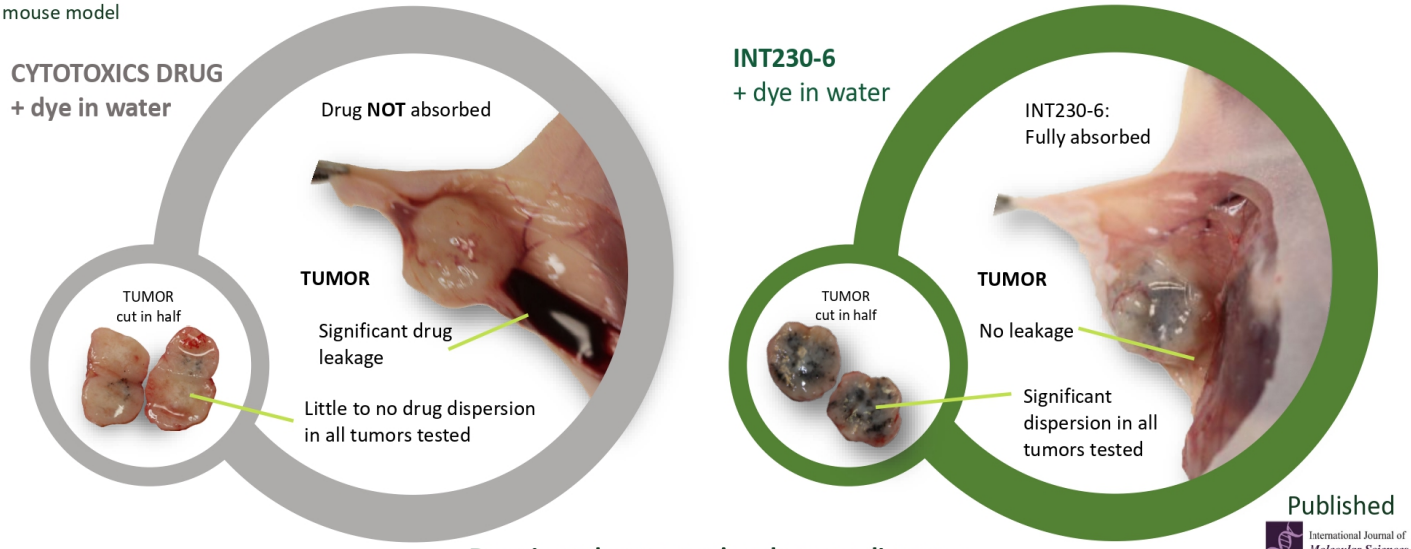
INT230-6: A Unique Anti-Cancer Therapy

A Water Solution That Kills Fatty or Stromal Tumors and Does Not Harm Healthy Tissue

Human pancreatic cancer in mouse model

*Tumors contain high percentages of fat and are under high pressure



Published in International Journal of Molecular Sciences

Dose is set by a tumor's volume or diameter

Design: Randomized, Placebo Controlled Phase 2 Window Trial In Presurgical Breast Cancer (BC): The INVINCIBLE Study

Patients Enrolled: 91 –Complete

INT230-6 **Randomized to either no treatment or saline injection**

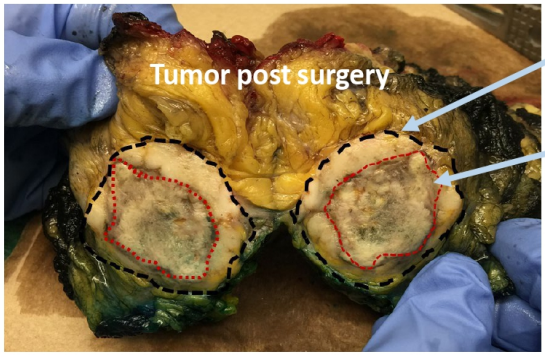
- **Site:** Ottawa Hospital
- **Investigator:** Dr. Angel Arnaout
- **Objectives**: Cause sufficient tumor necrosis prior to surgery to activate the immune system and determine INT230-6 safety presurgically
- **Final Goal:** Reduce the risk of disease recurrence

Our clinical results have been selected for Spotlight Oral Podium Presentation at:
The San Antonio Breast Cancer Symposium (SABCS) annual meeting December 2022:

Phase 2 INVINCIBLE Study:
INT230-6 Achieves Significant Cancer Necrosis with 1 or 2 Doses

Patient #14:
3.9 cm invasive ductal cancer:: 2 injections

May 6 — Injection #1: Dose 7.4 cc
May 13 — Injection #2: Dose 14.8 cc
May 20 — Surgery



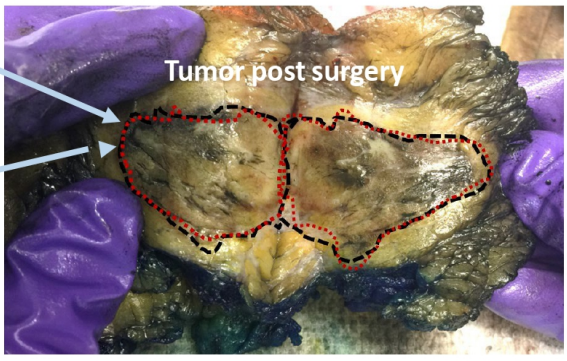
Final Pathology (significant necrosis ~85%)

Tumor Extent

Extent of Necrosis within Tumor

Patient #20:
4.4 cm invasive lobular cancer: 1 injection

May 27 — Dose 21.3 cc
June 16 — Surgery



Final Pathology (significant necrosis ~95%)
cancer is mostly ghost cells

Tumor death is dependent on total dose given per treatment and observed in multiple types of breast cancers

INT230-6 had Favorable Safety in the Presurgical BC Setting

- No surgery was delayed or cancelled
- No surgical procedure was altered
- No cosmetic differences noted

Pre vs. Post treatment
- In tumor: **increase in abundance of CD4+, CD8+, naïve T, B and NK T cells**
- In tumor microenvironment: **increase in CD8 T, CD4 T, naïve and B cells**
- Over 200 immune cell genes activated

- Mean wait time to surgery: 24 days (range 14-34 days) – normal timeframe
- 89% of adverse events were grade 1; all resolved within 7 days
- **Patient interest in the drug and acceptability was high; accrual was rapid**

Phase 2/3 Study Design Early Stage Breast Cancer

Design of Phase 3 Program in the larger sized tumors

INT230-6 + Standard of care (SOC is chemo/pembro) in TNBC and/or HER2+ versus SOC

- **Accelerated approval** using Pathological Complete Response (pCR) rates;
  - Data 4 months post enrollment
- **Full approval** show slower rate of recurrence of the cancer (EFS);
  - Data 3 years post enrollment

Attacking the Tumors – Sparing the Patient

IT-01 Phase 1 / 2 Study in Metastatic Disease –Enrollment Complete

ENROLLED: 110

Patients whose disease had progress after treatment with all approved therapies for their cancer, over 25 types of solid tumor types: ***Database now locked***

INT230-6 alone (64 patients)

With Keytruda (30 patients) (includes 2 who finished monotherapy)

With Yervoy (18 patients)

- **Injections up to 6 in a session into lung, liver, peritoneum, pancreas, breast, limbs, lymph, skin, muscles**
- **Dosed started with 5 mL once per month. Current dose 175 mL every two weeks.**

Intensity's results have been selected for Discussant Oral Podium Presentations at:

- The Annual American Society of Clinical Oncology: ASCO (2)
- The Annual Society for the Immunotherapy of Cancer: SITC
- The Annual Connective Tissue Society (sarcoma): CTOS (2)

15

Favorable Safety: Active Agents Remain in the Tumor

INT230-6

>95% of the active agents remain in the tumor relative to the drugs given IV

The retention is independent of the cancer type, location or size

Most common drug related adverse events are mild or moderate injection site pain, fatigue and brief nausea ~90 are low grade;

No grade 4 or grade 5 related adverse events.

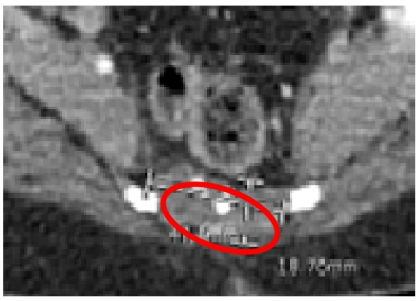
17

In Metastatic Disease injected Tumors Shrink in Volume Over Time
Shrinkage of uninjected tumors is observed

Tumors may appear longer prior to shrinking

Pre-treatment: 55.65 mm x 32.48 mm
September 2020

Post-treatment: 47.5 mm x 18.78 mm
March 2021



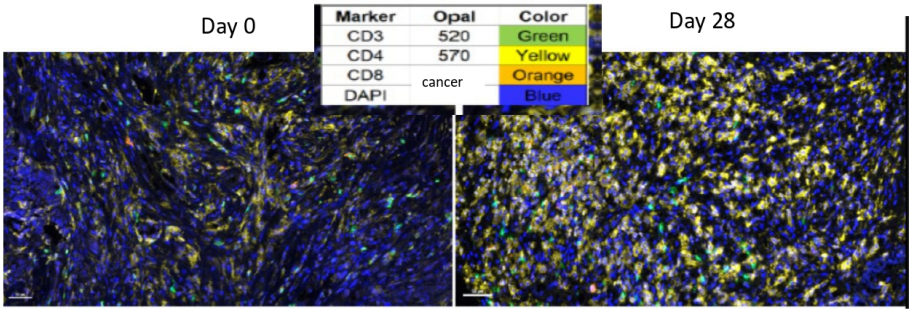
A scan of a monotherapy injected sarcoma tumor highlights tumor regression

Longest diameter declines 15%, whereas 2nd longest diameter declines 42%

Using WHO Criteria: Partial Response
Using RECIST Criteria: Stable Disease

Immune Activation Achieved in Non-immunogenic Cancers

Day 0

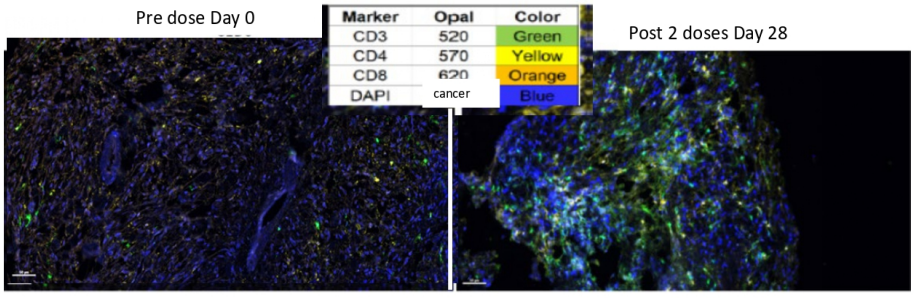


Day 28

After 2 doses of INT230-6 alone there is an increased anti-cancer immune cell influx into the tumor

Ovarian cancer

Pre dose Day 0

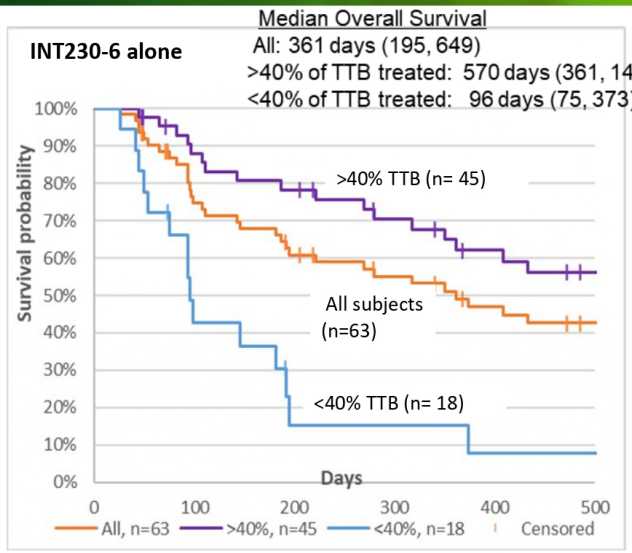


Post 2 doses Day 28

Liposarcoma

Survival Increases with Higher Dose Relative to the Patient's Tumor Burden

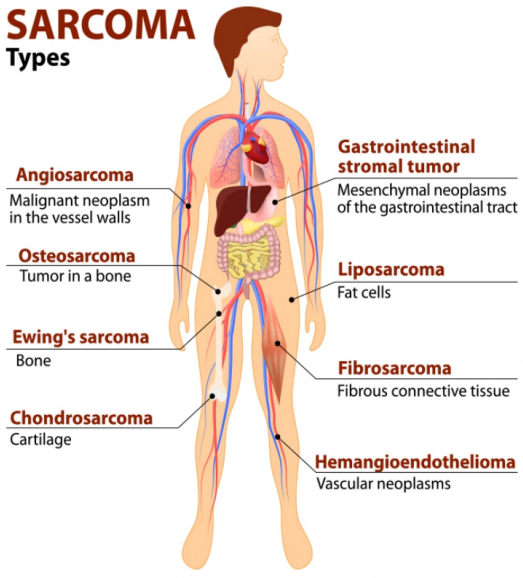
Increased dose relative to total tumor burden (TTB) shows prolonged survival

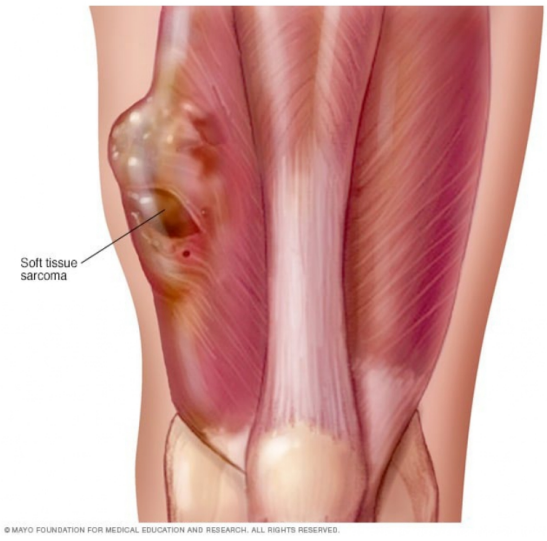


Monotherapy: 19 different cancers

An exploratory analysis of dose relative to a subject's incoming total tumor burden (TTB) was performed.

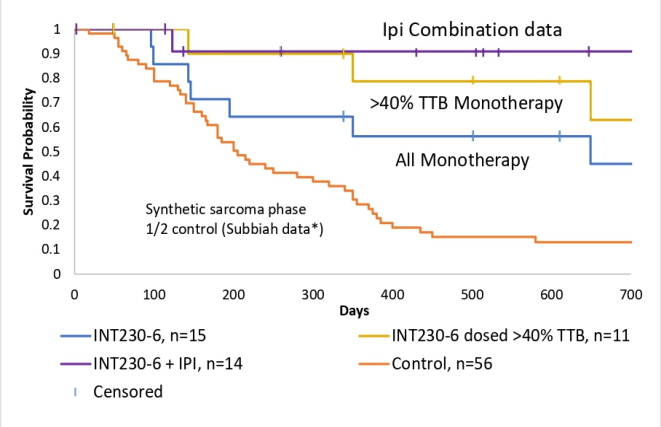
Sarcoma: A Deadly and Painful Cancer





In Sarcoma Median Overall Survival Increases with INT230-6 Alone or with Yervoy) Compared to a Synthetic Control

Kaplan Meier estimates sarcoma



Uninjected tumors shrank (abscopal responses)

	Synthetic Control (Subbiah data)	INT230-6 all	INT230-6 >40% TTB	INT230-6 + IPI
Median overall survival, CI	205 days	649 (195, 1352)	715 (649, 1352)	**Not reached median follow-up: 345 days**

Synthetic control created based on data from Subbiah, V, Scientific **Reports** | 6:35448

Phase 3 Trial Design For INT230-6 In Soft Tissue Sarcoma (STS)

Expected to Offer Survival Improvement compared to Current 2nd / 3rd Line SOC

- ≥ 18 years
- ECOG PS ≤ 2
- Locally recurrent, inoperable or metastatic Soft Tissue Sarcomas
- **2L/3L**
- measurable disease by RECIST 1.1
- at least one target tumor for injection

Must have had doxorubicin

2:1

n = up to 332

2

INT230-6 - Monotherapy

- **INT230-6 q2 weeks x 5 doses**
- **Maintenance q9 weeks x 22 months**

1

Standard of Care

- **Pazopanib: 800 mg PO qD**
- **Trabectedin: 1.5 mg/M² BSA as a 24 hour IV infusion q3 weeks**
- **Eribulin: 1.4 mg/M² BSA IV on Days 1 and 8 q3 weeks**

HR: 0.65

Overall survival (OS):
14.0 months Control
21.5 months INT230-6

Primary Endpoint:
•OS

Secondary Endpoints:
•Safety
•QoL
•OS for leiomyosarcoma
•OS for liposarcoma

Enrollment" 12 to 15 months
First look: ~12 months post

Data readout at 80% of events

Summary

- **INT230-6 represents a new treatment approach to solid tumors (diffusion based immunological cell killing) for metastatic disease and presurgical (neoadjuvant) settings**
  - Dose set by the total tumor burden – more personalized and spares the patient
  - Strong interest from: academic hospitals, major clinical oncology societies, big pharma and government

- INT230-6 has:
  - induced significant necrosis in large tumors following a single dose
  - Immune activation observed of non-immunogenic cancer types
  - Shown favorable safety and promising increased survival efficacy

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INTENSITY THERAPEUTICS

A NEW WEAPON IN THE WAR ON CANCER

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Thank you!