



SYNC-T[®] Platform
Personalized *In Situ*
Combination Immunotherapy

January 30, 2025

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All patients admitted to trials have signed an informed consent in accordance with the WMA Declaration of Helsinki involving ethical principles for medical research involving human subjects.



Syncromune is Developing Novel Combination Immunotherapies



Headquarters

Fort Lauderdale, FL



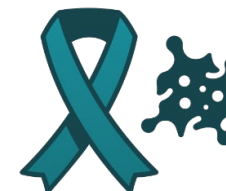
Employees

32



Financing

Recently Completed
\$100M Series A



Therapeutic Area

Metastatic Solid
Tumor Cancers

We aspire to develop a completely in situ immunotherapy platform technology optimized for solid tumor cancers that achieves high response rates with potentially curative efficacy



Syncromune[®] –Recent & Near-Term High-Value Milestones

Unprecedented Interim Phase 1 Data

- **Interim Data: 38% complete response (CR) and 85% overall response rate (ORR)**
- Plan to present final data at ASCO and publish in a major journal in 2025

Fast-Track Designation Granted by FDA

- FDA granted Fast-Track Designation for SYNC-T SV-102 for mCRPC

Phase 2a Enrollment Initiated for mCRPC

- **LEGION-100 Phase 2a trial for mCRPC enrollment initiated**
- Clinical development plan optimized for rapid enrollment

\$100M Series A December 2024

- Funds clinical development, device development, and drug co-formulation

A Different Approach to Address Current Treatment Limitations

The Problem

Low Response Rates in Solid Tumor Cancers

Only 15-20% of patients with metastatic solid tumor cancers respond to current systemic IV immunotherapy

Current Immunotherapies Not Effective in mCRPC

mCRPC is especially treatment resistant, with **overall response rates of 3-5%** when treated with systemic IV immunotherapy

High Rate of Autoimmune Side Effects with Combos

Combination IV immunotherapy has demonstrated slightly improved outcomes, but it's potential is limited due to systemic autoimmune side effects

Our Solution

SYNC-T, a new platform that simultaneously targets multiple mechanisms of cancer immune suppression

- *In situ* vaccine creation
- Multi-target biologic drug
- Drug infusion directly into tumor
- High concentration, low dose

mCRPC = metastatic castration-resistant prostate cancer

SYNC-T[®] Platform Therapy Design



Provide personalized *in situ* cancer vaccine for tumor antigen recognition



Utilize multi-target approach to address multiple immune suppression mechanisms simultaneously



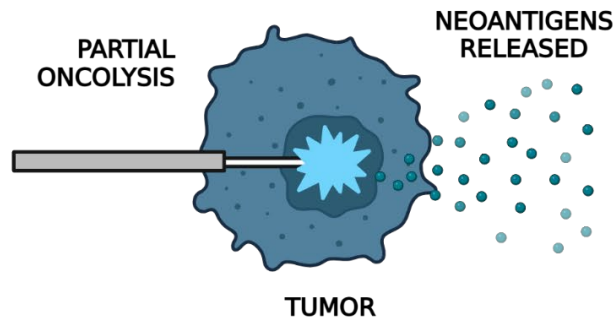
Focus on reversing immune suppression in the tumor microenvironment (TME) and tumor draining lymph nodes to create systemic anti-tumor immunity



Employ locoregional targeting that allows for lower dose administration, high local concentrations, less systemic exposure, and reduced toxicity

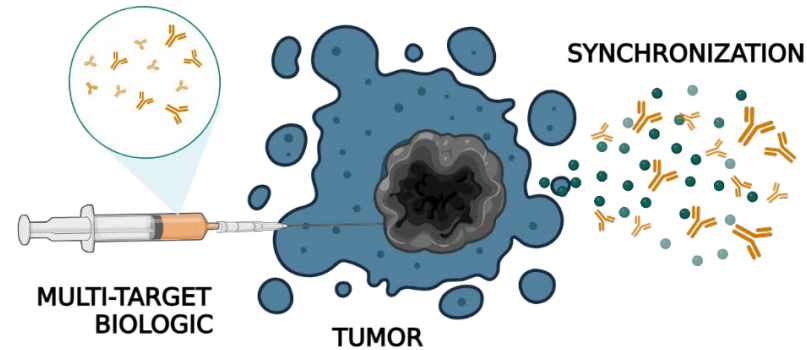
SYNC-T[®] Uses a Combination Approach to Overcome Treatment Resistance

Partial oncolysis of target tumor



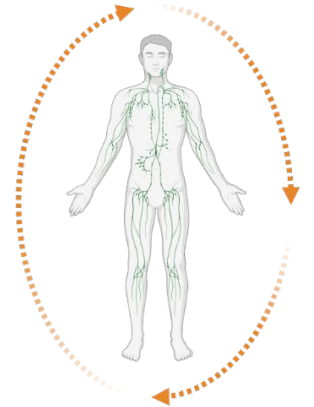
+

Infusion of multi-target biologic



=

T cell activation



- This combination approach is designed to empower the immune system to **create systemic anti-tumor immunity**
- Initial candidate is SYNC-T SV-102 for metastatic castration-resistant prostate cancer (mCRPC)

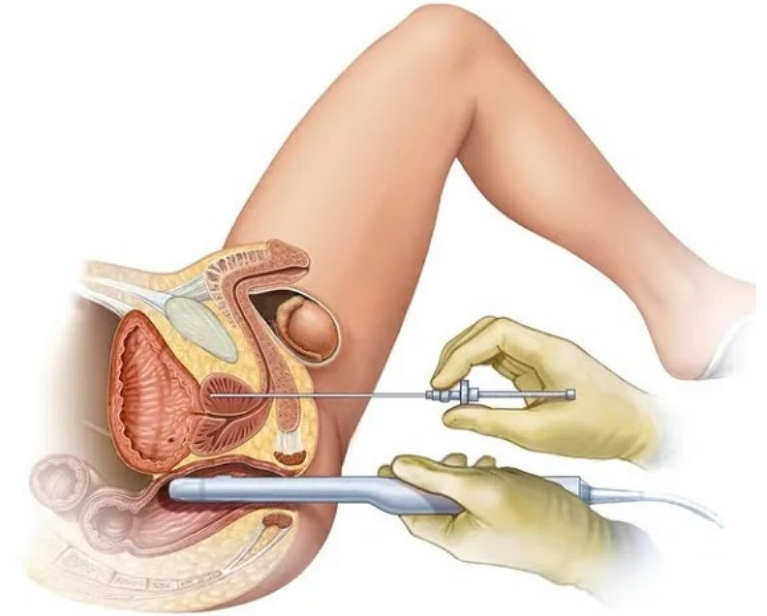
Emerging Phase 1 data demonstrates that the SYNC-T platform can potentially improve both safety and efficacy in comparison to combination systemic immunotherapies



SYNC-T[®] for mCRPC

Seamless integration into Urology Practices

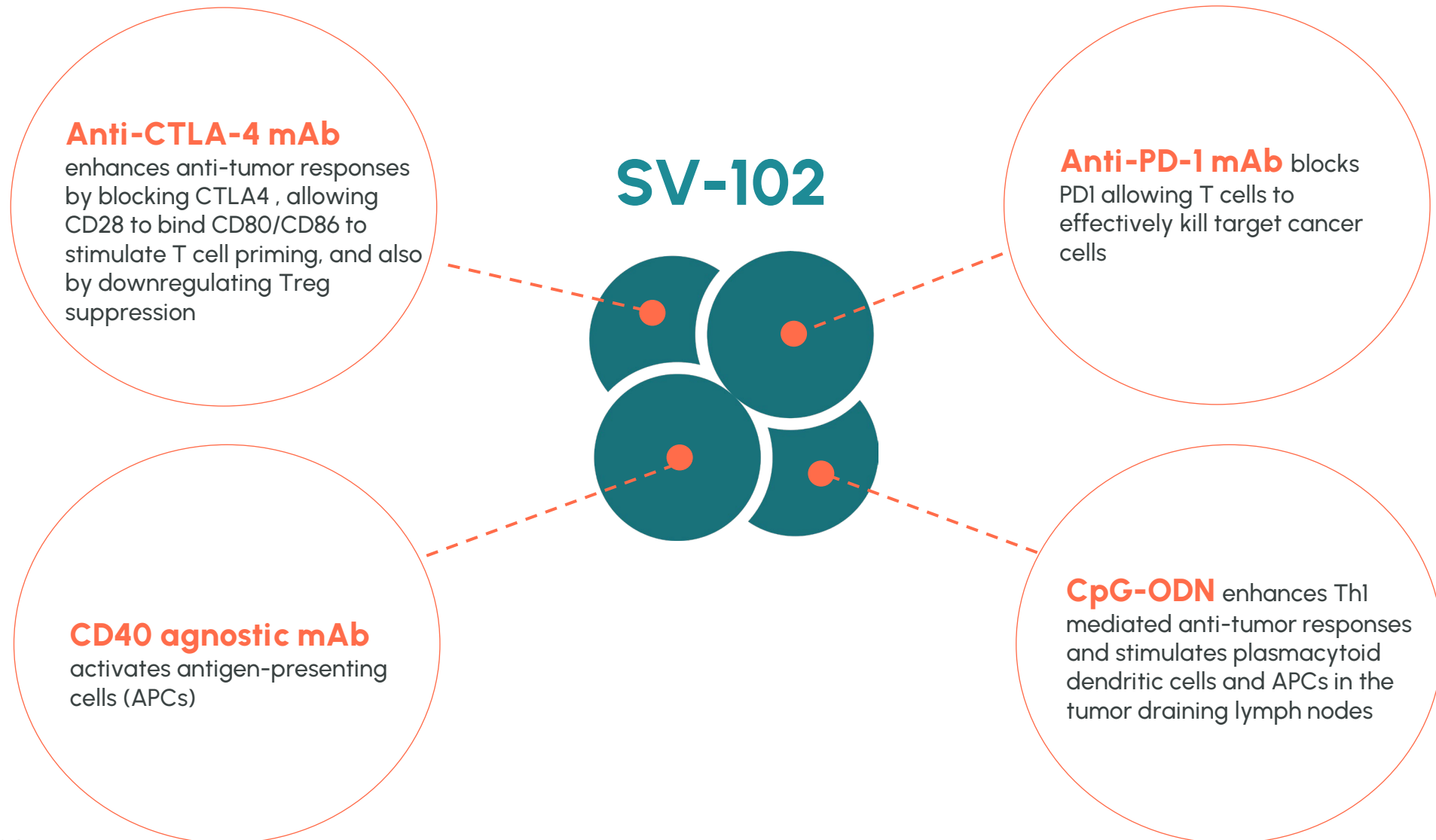
- We believe that SYNC –T Therapy will be welcomed by Urologists as a familiar procedure they can readily provide to their patients with mCRPC, allowing them to keep their patients rather than having to continue to refer them to an Oncologist for end-of-life palliative care.
- SYNC-T Therapy leverages clinical procedural skills that are already routine for Urologists:
 - Prostate or surrounding tissue: MR and/or TRUS guided transperineal needle placement
 - Distant soft tissue metastases : CT Guided needle placement by Interventional Radiologist



Urologists routinely perform prostate biopsies and other procedures using a transperineal approach

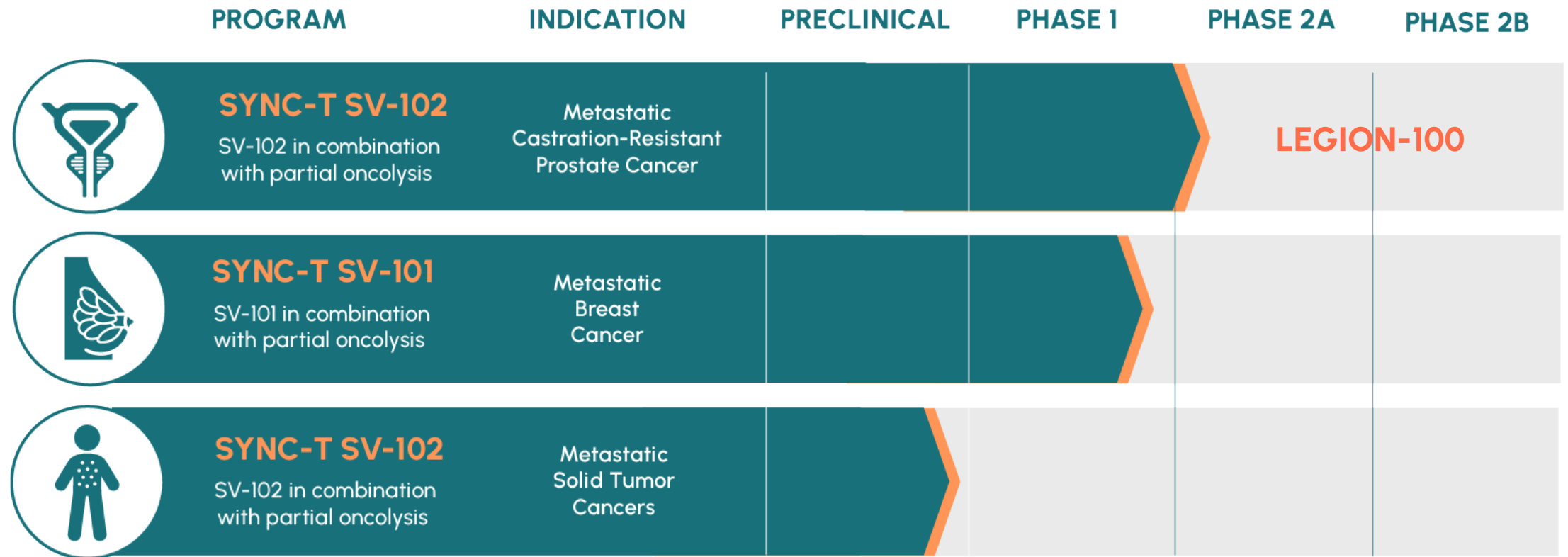
SYNC-T® SV-102: Fixed-Dose Combination of 4 APIs

Best In Class and/or First In Class Molecules



SYNC-T[®] Platform Development Pipeline

Can be tailored to treat virtually all solid tumor cancers



LEGION-100 SYNC-T SV-102 Phase 2a Trial for mCRPC commenced enrollment January 2025

SYNC-T[®] is a Platform That May Treat Many Solid Tumor Cancers

Potential to Build Out Pipeline for Several Multi-Billion-Dollar Markets

Initial indication:

Metastatic Castration-Resistant Prostate Cancer (mCRPC)



US Market (prevalence)

- 52,976 patients with mCRPC
- **Market > \$15 billion**



Metastatic Breast Cancer (mBCa)

US Market (prevalence)

- 168,000 patients with mBCa
- Market > \$80B



Metastatic Non-Small Cell Lung Cancer (mNSCLC)

US Market (prevalence)

- 123,515 patients with mNSCLC
- Market > \$40B



Metastatic Bladder Cancer (mBC)

US Market (prevalence)

- 25,000 patients with Stage 4 mBC
- Market > \$5B

Highly Experienced Team – Public Company Ready

EXECUTIVE TEAM



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Executive Chairman



Eamonn Hobbs

President &
Chief Executive Officer



Gerald Andriole, M.D.

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Susan Drexler

Chief Financial Officer



Agustin Gago

Chief Operating Officer



Gregory Champion, Esq.

Chief Legal Officer



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- The Joe Shapiro Professor of Medicine Professor, Division of Oncology & Hematology Non-Hodgkin Lymphoma, Hodgkin Disease, Chronic Lymphocytic Leukemia, UNMC
- Served as President of ASCO (1996-97) and President of ASBMT (2000-01)
- Authored or co-authored more than 500 articles and 100 book chapters and is the editor/co-editor of 27 books



**George C.
Prendergast, Ph.D.**

Advisor

- President and CEO of the Lankenau Institute for Medical Research (LIMR)
- Former editor-in-chief of Cancer Research (journal of AACR)
- Has developed a new immune therapy that is in Phase II trials



Suming Wang, M.D., Ph.D.

Advisor

- Founded Shanghai Mingda Biotech, an immune therapy company in 2014
- Former CEO of Shanghai East International Medical Center
- Vice President of NewLink Genetics from 1999-2008



**David
Vaughan, M.D.**

Advisor

- Experience performing intratumoral immunotherapy in metastatic prostate cancer
- Former Partner of Orlando Urology Associates
- Former Chairman of Dept. of Urology at Florida Hospital & Winter Park Hospital

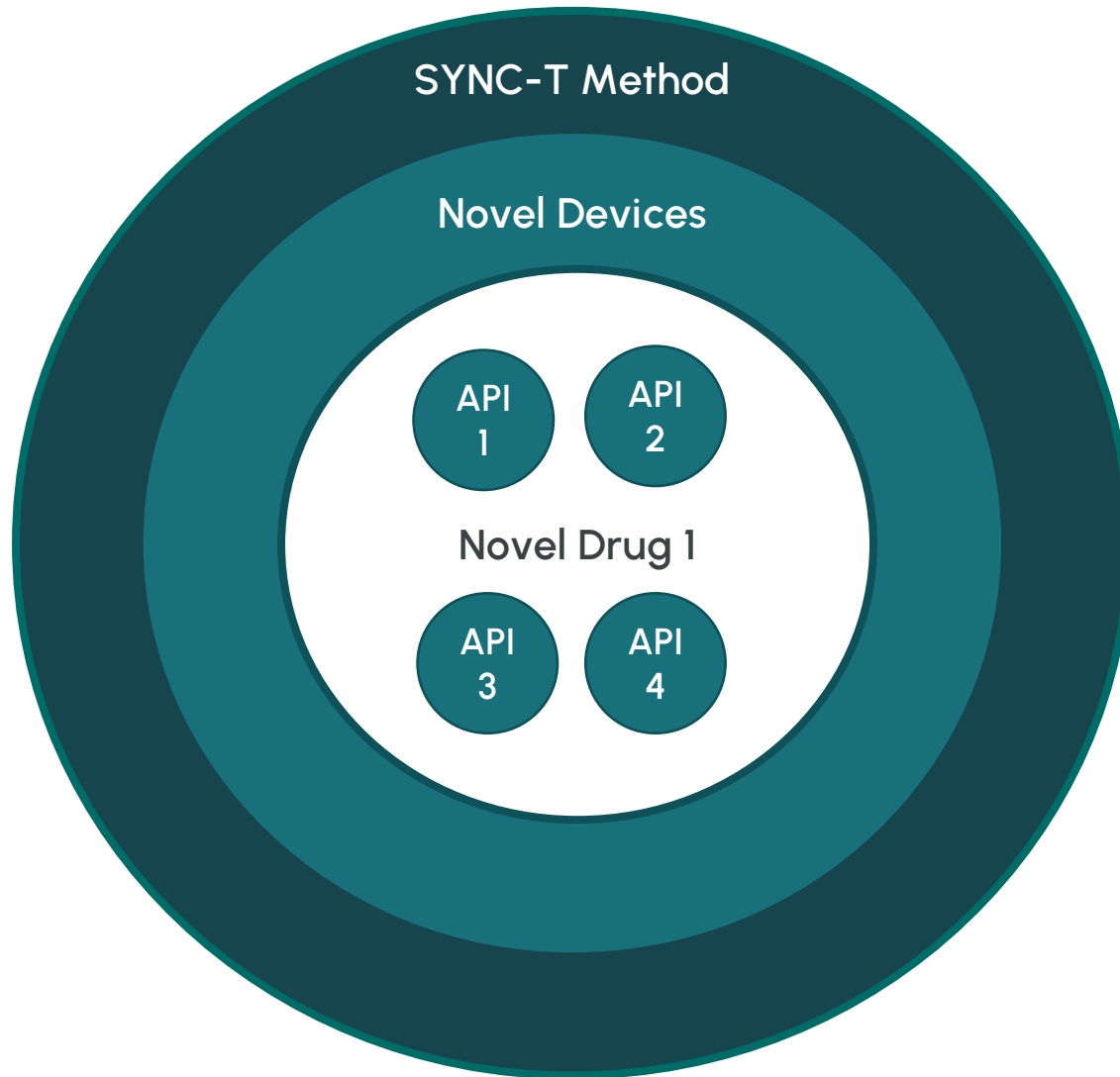


**Richard
Harris, M.D.**

Advisor

- Board-certified urologist with expertise in the treatment of advanced prostate cancer and health policy
- Involved in the clinical drug development and research of over 70 drug trials
- Past President of LUGPA (Large Urology Group Practice Association) Board of Directors

IP Strategy - Layers of Patent Protection



- Independent FTO analyses conducted on drugs, devices and methods
- Each novel biologic API has recently issued and/or pending Composition of Matter Patent Protection
- Each novel fixed dose combination biologic drug has pending Composition of Matter Patent Protection for novel combination of 4 Targets (MOA) with 4 Novel APIs plus Novel Coformulation chemistry.
- Pending utility patents for novel Oncolysis Device generator and consumable system.
- Pending method patents for SYNC-T procedural methods including oncolysis and intratumoral/locoregional infusion

SYNC-T[®] SV-102 Phase 1 Interim Data

Presented at AACR Annual Meeting, April 2024

SYNC-T[®] SV-102 Phase 1 Trial for mCRPC Overview

Eligibility Criteria

- Metastatic histologically confirmed mCRPC
- Failure of previous treatment with one or more approved second-generation androgen-receptor-pathway inhibitors with or without prior chemotherapy or refused hormone therapy and chemotherapy
- Measurable disease by RECIST criteria

Trial Design

- Up to 12 cycles of SYNC-T SV-102 at 4-week intervals to achieve best response
- Oncolysis combined with SV-102 fixed dose of 15 ml volume
- Baseline imaging of bone scan and/or PET/CT, and MRI of prostate
- Response assessment every 8 weeks

Objectives

- Primary endpoints: evaluate safety and toxicity
- Secondary endpoints: ORR by RECIST 1.1, rPFS by PCWG3, OS, ORR by iRECIST

Follow Up Period

- Durability of response measured every 12 weeks after completion of therapy
- 12 month follow up period after last treatment cycle

Phase 1 Overview



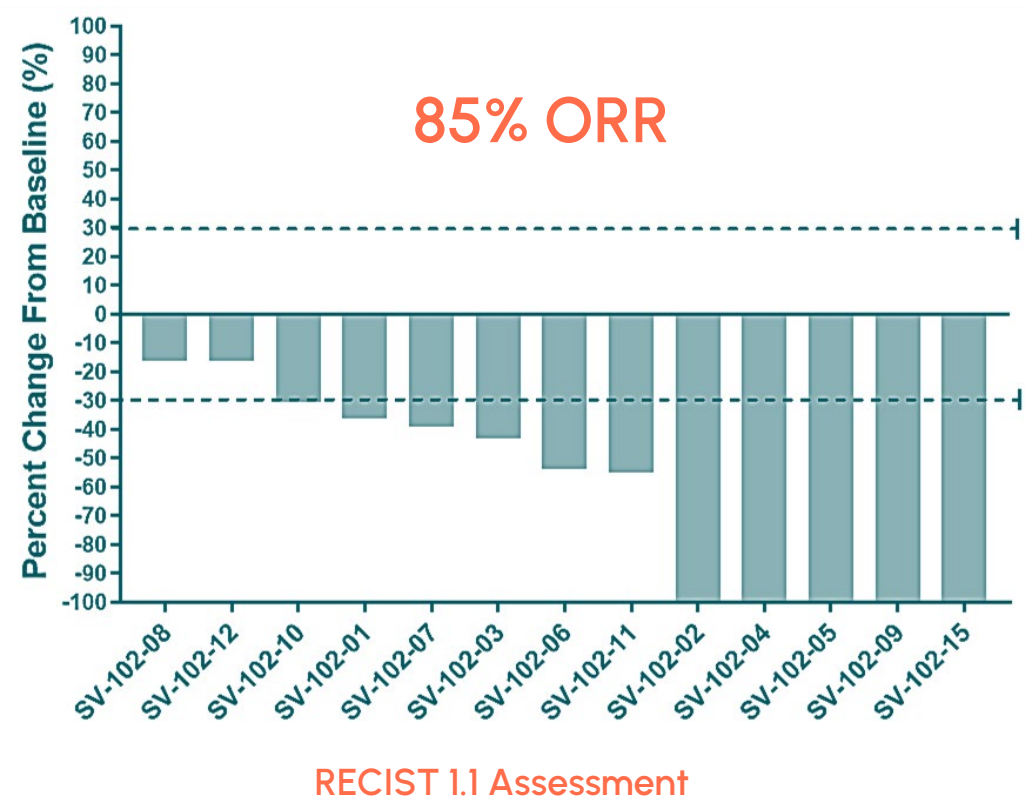
SYNC-T[®] SV-102 Patient Characteristics

Heavily Pre-Treated Patients With Extensive Metastatic Disease

Characteristic	Subjects n = 15
Median age (range)	61 (49-74)
Race, %	
White	60
Hispanic	33
Black	7
ECOG, %	
PS-0	40
PS-1	53
PS-2	7
Prior Therapy, %	
ADT and/or 2 nd generation anti-androgen or subject refused	100
Chemotherapy	23
Radiation Therapy	38
Immunotherapy	15

● Compelling Interim Phase 1 Data for mCRPC With 38% Complete Response

Presented at the 2024 American Association for Cancer Research (AACR) Annual Meeting



Best Response in Evaluable Subjects (n=13)	
Complete Response	38%
Partial Response	46%
Stable Disease	15%
Progressive Disease	0%
Overall Response Rate	85%
Complete Resolution of Bone Metastases	54%

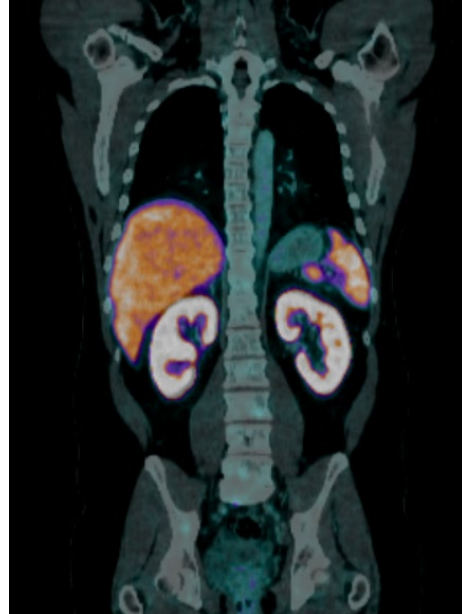
All CRs had a PSA < 2 when they achieved their response

Subject SV-102-09: Complete Response

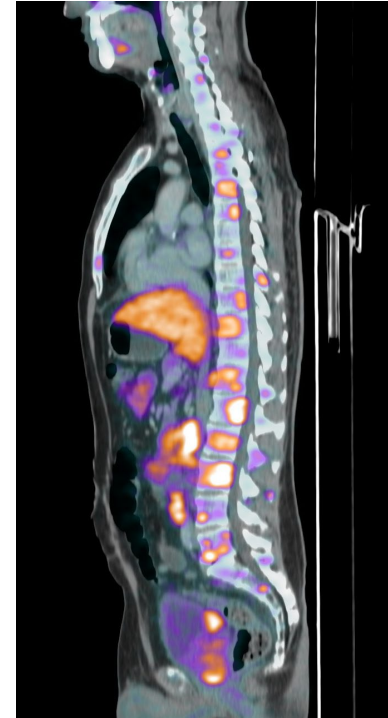
- Subject was confirmed via RECIST as a Complete Response
- Tumor was PD-1/ PD-L1 NEG and proficient MMR
- rPFS 200+ days



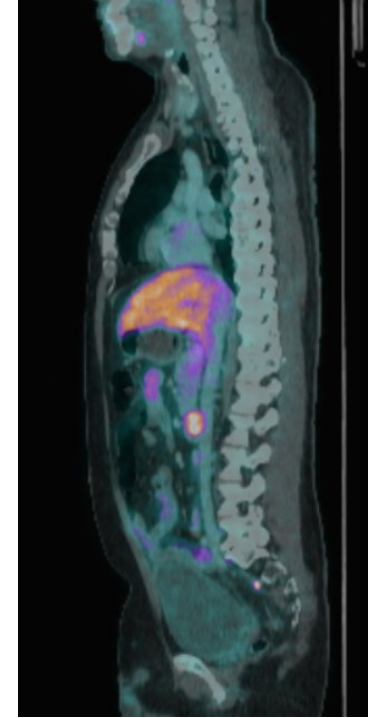
PRE-THERAPY. May 2023 coronal PSMA PET/CT shows extensive bone metastases (greater than 50)



POST-THERAPY. December 2023 coronal PSMA PET/CT shows complete resolution of all bone metastases



PRE-THERAPY. May 2023 sagittal PSMA PET/CT shows extensive bone metastases

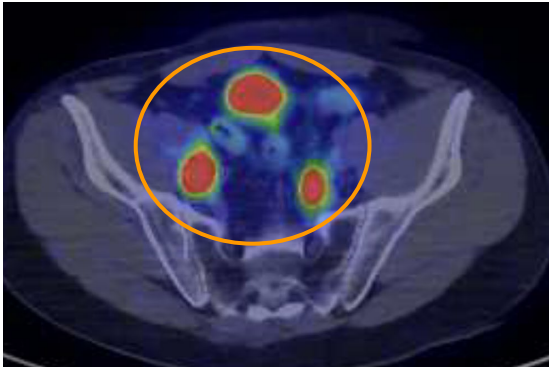


POST-THERAPY. December 2023 sagittal PSMA PET/CT shows complete resolution of all bone metastases

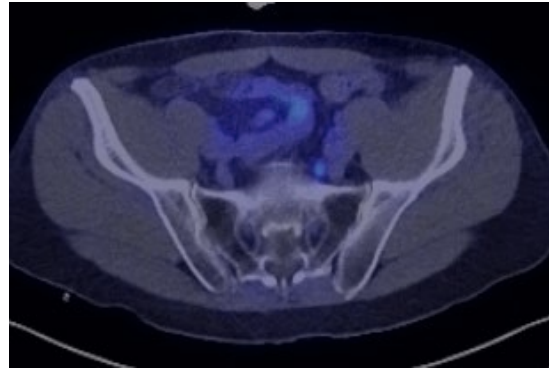
Complete resolution of > 50 bone metastases

Subject SV-102-04: Complete Response

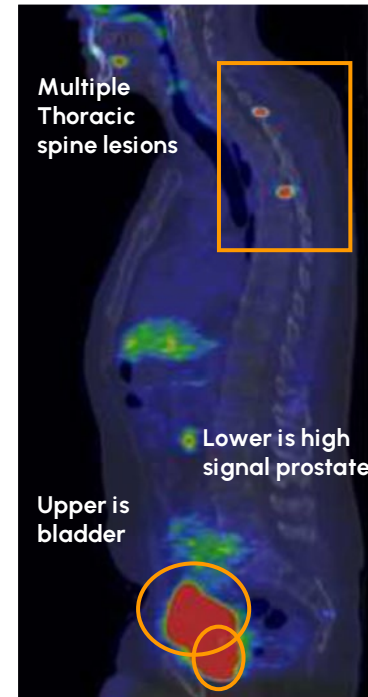
- After Cycle 4, subject was confirmed via RECIST as a **Complete Response** with resolution of bone metastases, lymph node metastases and prostate
- rPFS 261+ days



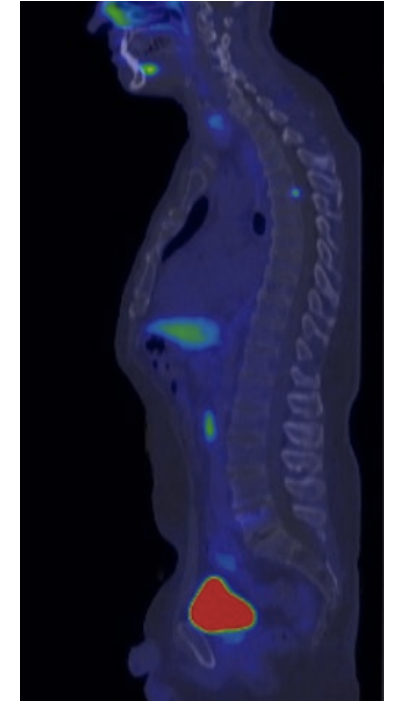
PRE-THERAPY. 3/2023 axial view shows a markedly abnormal PSMA PET/CT, high SUV in prostate, pelvic lymph nodes, and spine



POST-THERAPY. 9/2023 axial PSMA PET/CT showing minimal signal uptake in posterior aspect on T4



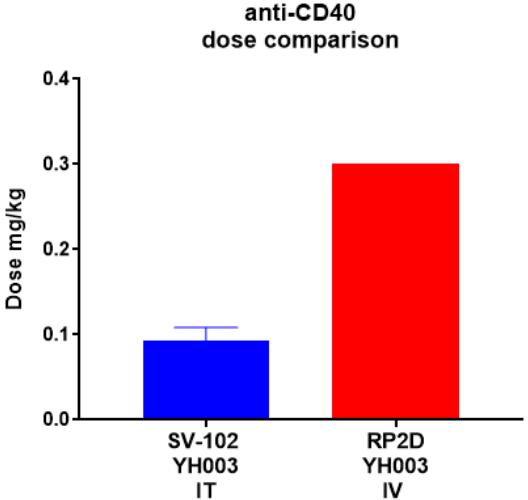
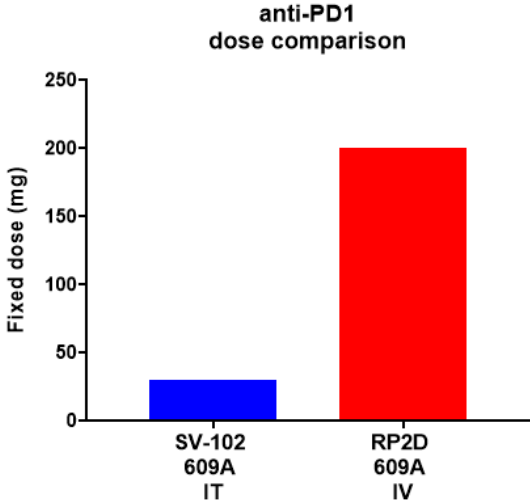
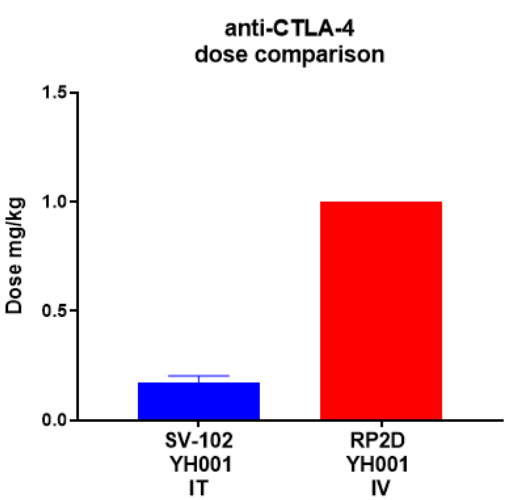
PRE-THERAPY. 3/2023 sagittal view shows a markedly abnormal PSMA PET/CT, high SUV in prostate, pelvic lymph nodes, and spine



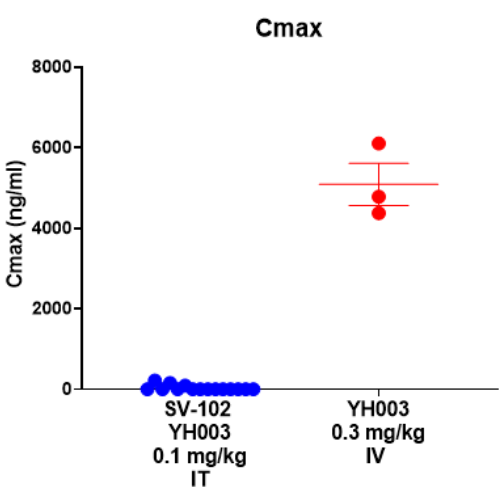
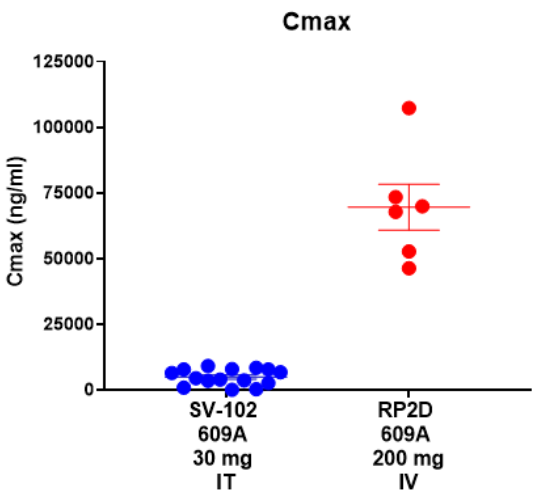
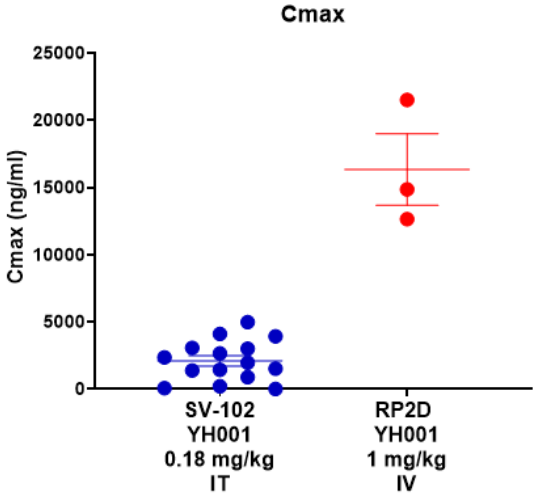
POST-THERAPY. 9/2023 sagittal PSMA PET/CT showing resolution of disease

Lower Dose & Exposure of SV-102 APIs Compared to Systemic Delivery

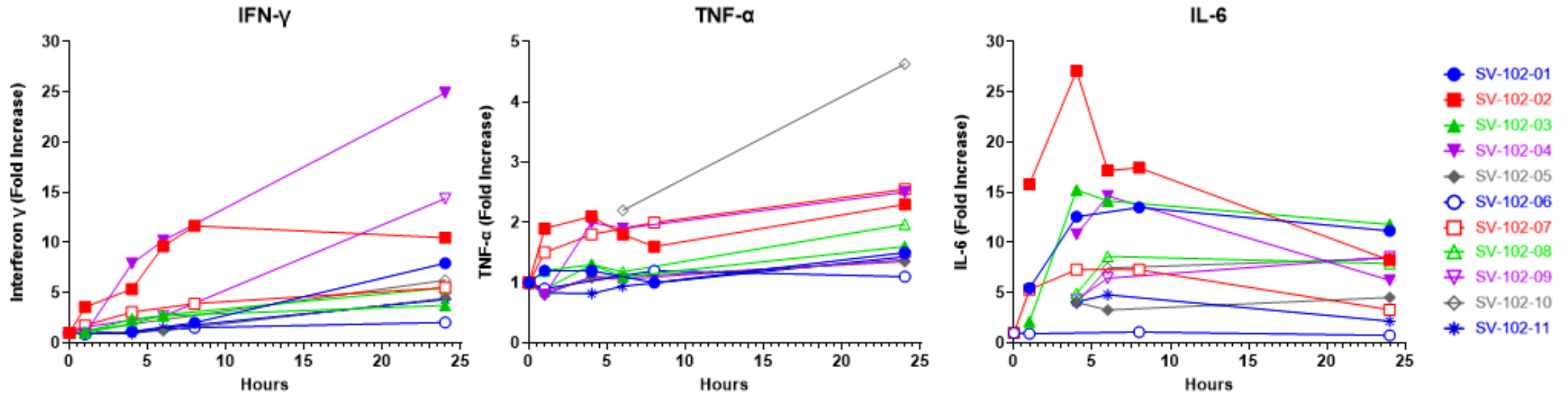
APIs in SV-102 are dosed at much lower levels than IV RP2D



Much lower systemic exposure is observed



Anti-Tumor Cytokines Are Rapidly Induced by SYNC-T Therapy*



- Pro-inflammatory cytokines increase during the first 24 hours after SYNC-T Therapy
- IFN γ , TNF α and IL-6 all show significant increases from pre-treatment

* Data from first 11 subjects



Favorable Safety Profile With No Grade 3 or 4 Immune-Related AEs

Term	All TEAEs		Grade 1+2 TEAEs		Grade ≥3 TEAEs	
	(N=15) n (%)	Events	(N=15) n (%)	Events	(N=15) n (%)	Events
Any Treatment Emergent Adverse Events (TEAEs)	13 (86.7)	31	12 (80.0)	29	2 (13.3)	2
Fever	3 (20.0)	4	3 (20.0)	4	0	0
Hematuria	3 (20.0)	3	3 (20.0)	3	0	0
Diaphoresis	2 (13.3)	2	2 (13.3)	2	0	0
Urinary Retention	2 (13.3)	2	1 (6.7)	1	1 (6.7)	1
Vomiting	2 (13.3)	2	2 (13.3)	2	0	0
Diarrhea	1 (6.7)	1	1 (6.7)	1	0	0
Acute Urinary Retention	1 (6.7)	2	1 (6.7)	2	0	0
Anemia	1 (6.7)	1	1 (6.7)	1	0	0
Chest Pain	1 (6.7)	1	1 (6.7)	1	0	0
Diarrhea	1 (6.7)	1	1 (6.7)	1	0	0

Term	All TEAEs		Grade 1+2 TEAEs		Grade ≥3 TEAEs	
	(N=15) n (%)	Events	(N=15) n (%)	Events	(N=15) n (%)	Events
Fatigue	1 (6.7)	1	1 (6.7)	1	0	0
Hepatic Enzymes Increased	1 (6.7)	1	1 (6.7)	1	0	0
Myalgias	1 (6.7)	2	1 (6.7)	2	0	0
Polydipsia	1 (6.7)	1	1 (6.7)	1	0	0
Rash Cutaneous	1 (6.7)	1	1 (6.7)	1	0	0
Rectal Discomfort	1 (6.7)	1	1 (6.7)	1	0	0
Right Shoulder Fracture	1 (6.7)	1	1 (6.7)	1	0	0
Skin Squamous Cell Carcinoma	1 (6.7)	1	1 (6.7)	1	0	0
Spinal Cord Compression	1 (6.7)	1	0	0	1 (6.7)	1
Urethral Discomfort	1 (6.7)	1	1 (6.7)	1	0	0
Urinary Tract Infection	1 (6.7)	1	1 (6.7)	1	0	0

Majority of TEAEs were transient, flu-like symptoms that resolved quickly and were easily managed

Compelling Response Rates & Tolerability vs. Previous mCRPC Immunotherapy Trials

Previous mCRPC immunotherapy trials have demonstrated low response rates, and combination systemic immunotherapies had significant rates of toxicity and discontinuation of therapy due to adverse events

Trial	# Subjects	CR	ORR	≥ Grade 3 AEs	Discontinue d/t AE
SYNC-T SV-102 Intratumoral anti-PD-1 + anti-CTLA-4 + CD40 +CpG	N = 13	38%	85%	7%	0%
STARVE-PC Systemic anti-PD-1 + anti-CTLA-4	N = 30	6 – 7%	0 – 25%	46 – 53%	20 – 40%
CHECKMATE 650 Systemic anti-PD-1 + anti-CTLA-4	N = 90	6 – 7%	10 – 25%	42 – 53%	33 – 36%
KEYNOTE 199 Systemic anti-PD-1	N = 258	1%	3 – 5%	15%	5%
IMPACT Immunotherapy Provenge®	N = 512	0%	0.3%	7%	0.9%

SYNC-T SV-102 has demonstrated the potential to effectively combine multiple immunotherapies while avoiding major systemic autoimmune side effects

LEGION-100 Phase 2a for mCRPC

Multi-Center 2-Part Dose Escalation and Dose Optimization Trial



LEGION-100 Phase 2a Trial for mCRPC – Now Enrolling

High-Level Study Design



Part 1: Up to 18 subjects (depending on DLTs) enrolled across 3 cohorts

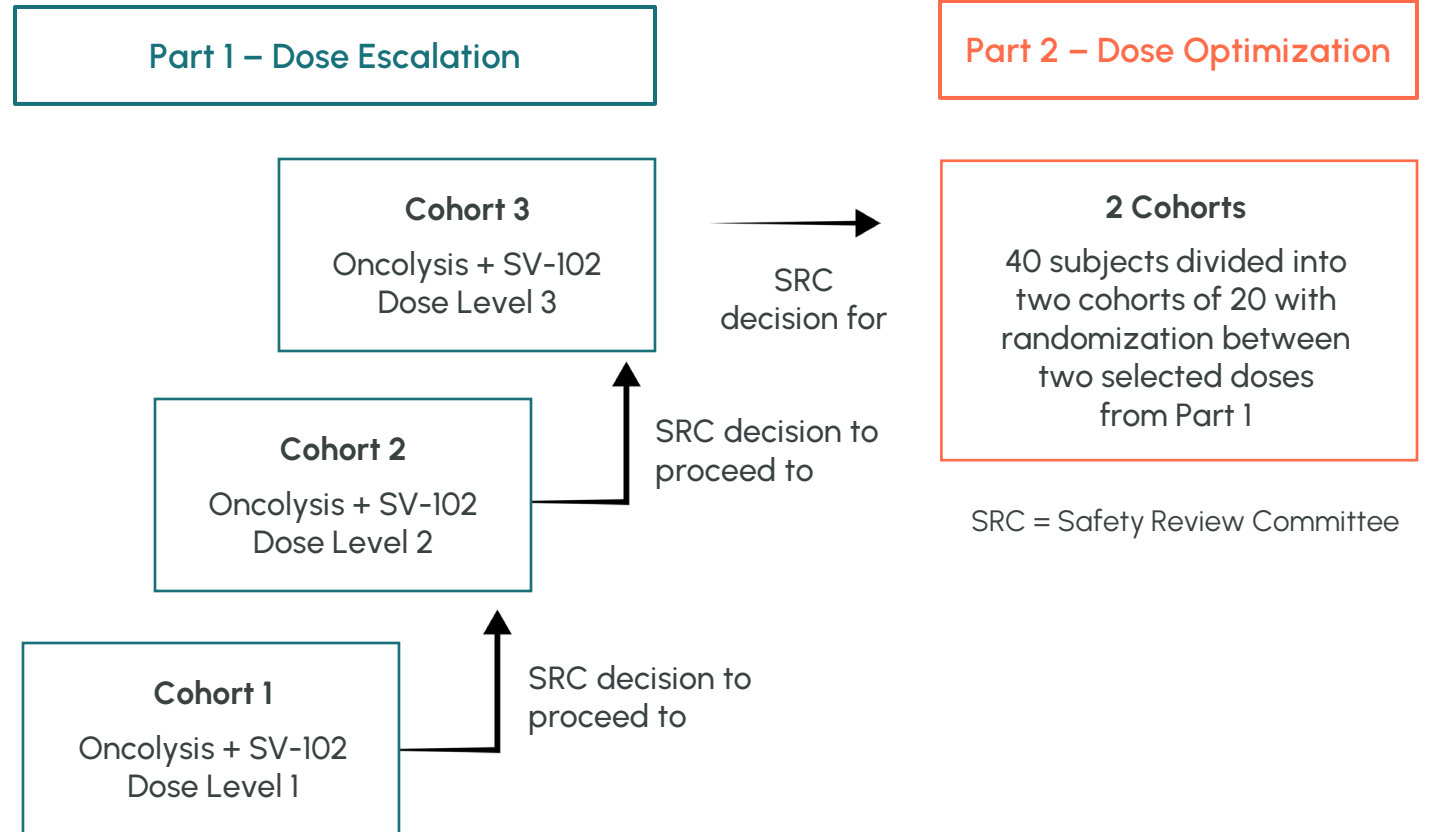


Traditional 3 + 3 dose escalation rule

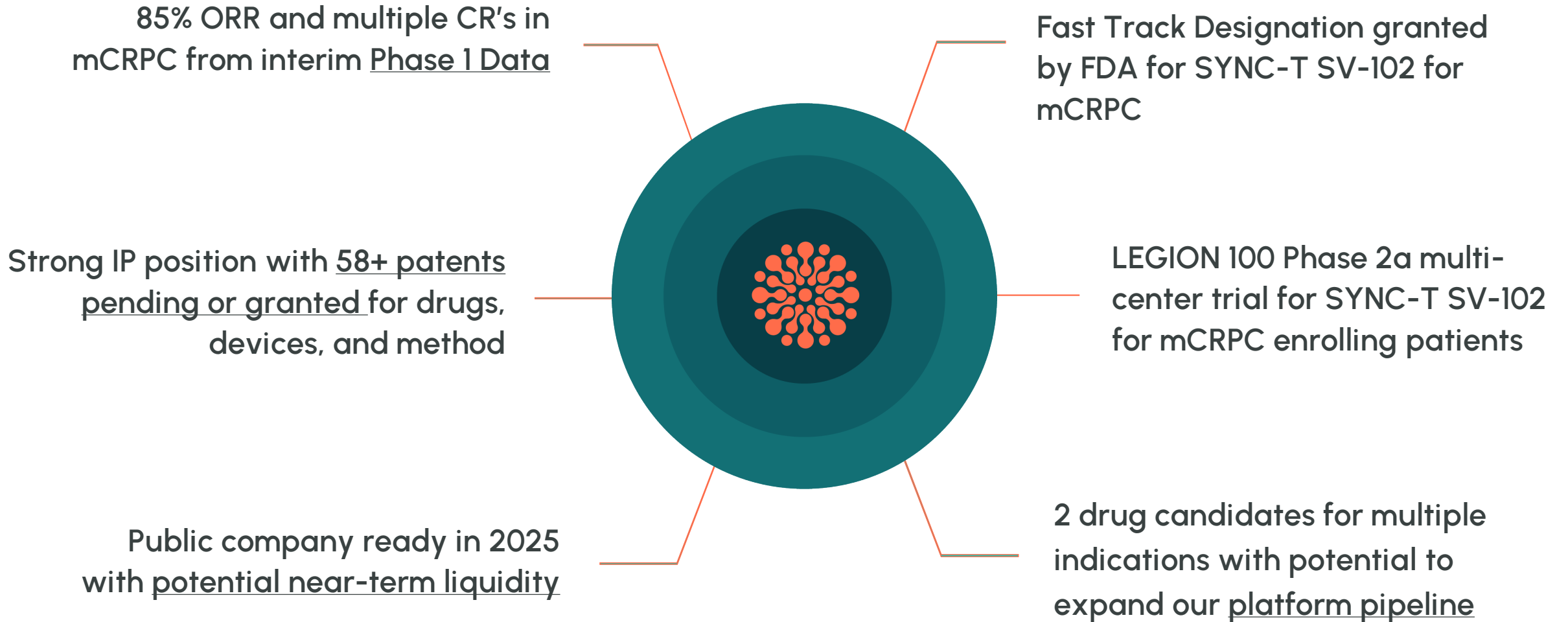


Part 2: 40 subjects randomized 1:1 with 2 doses from dose escalation

Study Schematic



Investment Drivers



Thank You

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