

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): January 6, 2023

TRACON Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction  
of incorporation)

001-36818

(Commission File Number)

34-2037594

(IRS Employer Identification No.)

4350 La Jolla Village Drive, Suite 800  
San Diego, California

(Address of principal executive offices)

92122

(Zip Code)

Registrant's telephone number, including area code: (858) 550-0780

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:

- ☐ 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 Securities Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	TCON	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 2.02 Results of Operations and Financial Condition.**

Charles P. Theuer, M.D., Ph.D., President and Chief Executive Officer of TRACON Pharmaceuticals, Inc. (“TRACON”), and other executive officers will be presenting information that includes an estimate of TRACON’s cash, cash equivalents and short-term investments and outstanding debt principal balances as of December 31, 2022, at various upcoming meetings beginning January 9, 2023. The information is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information is unaudited and preliminary and is subject to completion of financial closing procedures. Additional information and disclosure would be required for a more complete understanding of TRACON’s financial position and results of operations as of December 31, 2022.

**Item 7.01 Regulation FD Disclosure.**

Charles P. Theuer, M.D., Ph.D., and other executive officers will be presenting the information attached as Exhibit 99.1 to this Current Report on Form 8-K at various upcoming meetings beginning January 9, 2023.

By furnishing the information in this Current Report on Form 8-K, TRACON makes no admission as to the materiality of any information in this report. The information contained in this Current Report on Form 8-K and Exhibit 99.1 hereto is intended to be considered in the context of TRACON’s filings with the Securities and Exchange Commission and other public announcements that TRACON makes, by press release or otherwise, from time to time. TRACON undertakes no duty or obligation to publicly update or revise the information contained in this Current Report on Form 8-K or Exhibit 99.1 hereto, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosure.

The information provided in Item 2.02 and Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, 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 it be deemed incorporated by reference into any of the TRACON’s filings 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.**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Corporate Presentation, dated January 2023.</a>
104	Cover page Interactive Data File (embedded within the Inline XBRL document).

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## 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.

Date: January 6, 2023

**TRACON Pharmaceuticals, Inc.**

By: /s/ Charles P. Theuer, M.D., Ph.D.

Name: Charles P. Theuer, M.D., Ph.D.  
*President and Chief Executive Officer*

# TRACON PHARMACEUTICALS

## Investor Presentation

### January 2023



NASDAQ: TCON

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# Forward-Looking Statements

This presentation contains statements that are, or may be deemed to be, "forward-looking statements." In some cases these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," "potential," or, in each case, their negatives or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition, business strategy, current and prospective product candidates, planned clinical trials and preclinical activities, potential events and activities under existing collaboration agreements, estimated market opportunities for product candidates, research and development costs, current and prospective collaborations, timing and likelihood of success of development activities and business strategies, plans and objectives of management for future operations, and future results of anticipated product development efforts, including potential benefits derived therefrom. These statements involve substantial known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risks associated with conducting clinical trials, whether any of our product candidates will be shown to be safe and effective, our ability to finance continued operations, our reliance on third parties for various aspects of our business, the potential early termination of collaboration agreements, competition in our target markets, our ability to protect our intellectual property, our ability to execute our business development strategy and in-license rights to additional pipeline assets, and other risks and uncertainties described in our filings with the Securities and Exchange Commission, including under the heading "Risk Factors". In light of the significant uncertainties in our forward-looking statements, you should not place undue reliance on these statements or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements contained in this presentation represent our estimates and assumptions only as of the date of this presentation and, except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this presentation.

This presentation also contains estimates, projections and other information concerning our industry, our business, and the markets for our drug candidates, as well as data regarding market research, estimates and forecasts prepared by our management. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

This presentation discusses product candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the use for which such product candidates are being studied.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

## TRACON Pharmaceuticals Summary

- Potential best-in-class PD-L1 checkpoint inhibitor envafolimab dosing in ENVASARC pivotal trial in sarcoma in US with BLA filing expected in 2024. **Positive interim efficacy and safety data released in December 2022.** Approved in China.<sup>1</sup>
- Clinical stage pipeline includes:
  1. CTLA-4 antibody in P2
  2. DNA repair inhibitor in P2 in collaboration with NCI
  3. CD73 antibody completed P1 in combination with Tecentriq®
- Pipeline driven by TRACON's CRO-independent clinical development and commercialization capabilities (Product Development Platform) that also serves as a solution for ex-U.S. and U.S. companies
  - Five collaborations since 2016 (J&J, Alkermes Oncology/3D Medicines, Eucare and I-Mab)
  - Capacity and appetite for more deals now
- Low financial burn rate and current capital provide runway into Mid-2023 past expected interim ENVASARC pivotal trial data, ICC arbitration result, and partner milestone payment



<sup>1</sup> Approved and marketed in China by 3D Medicines and Alkermes Oncology. TRACON does not have rights outside North America.

# Investment Highlight #1: Envafolimab, a Potential Best-in-Class Checkpoint Inhibitor in Pivotal Trial in Unmet Need Indication

## ENVAFOLIMAB

**Potential for Near-term U.S. Commercialization of the 1<sup>st</sup> Approved PD-(L)1 Subcutaneous Checkpoint Inhibitor**

Rapid low volume subcutaneous injection without an adjuvant that is more convenient, less invasive and safer than IV therapy



(1) Assuming successful pivotal study  
(2) Third party estimate sponsored by TRACON

### Rapid Execution

ENVASARC pivotal trial began dosing in sarcoma in 4Q 2020 following successful FDA meeting

### Orphan Drug and Fast Track Designation in Sarcoma









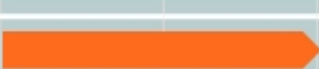


### Fast to Market Strategy

Expect ENVASARC interim data in 2023, final data and U.S. BLA in 2024 and launch in 2025<sup>(1)</sup>

### Financial Upside

Peak U.S. annual revenue estimated at >\$300M in initial indications using parity pricing to approved PD-(L)1 products<sup>(2)</sup>  
ENVASARC pivotal trial cost estimated at <\$25M through TRACON Product Development Platform.

## Investment Highlight #2: Pipeline of Clinical Stage Assets

Compound	Indication		Pre-Clinical	Phase 1	Phase 2	Pivotal
Envafolimab <sup>1</sup>	Sarcoma	 				
YH001 <sup>2</sup>	Sarcoma Others					
TRC102	Lung Others					
TJ4309 <sup>3</sup>	Solid Tumors					
Bispecifics <sup>3</sup>	Solid Tumors					

<sup>1</sup> Partnered with 3D Medicines Co., Ltd. (3D Medicines) and Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab). TRACON does not have rights to Envafolimab outside of North America or for indications other than sarcoma.

<sup>2</sup> Partnered with Eucure Biopharma, a division of Biocytogen. TRACON has rights in North America in sarcoma and multiple other indications. Represents a Phase 1/2 clinical trial for YH001 in combination with envafolimab and doxorubicin.

<sup>3</sup> TRACON has certain royalty and non-royalty rights with respect to TJ4309; TRACON is responsible for development and commercialization of up to 5 bispecific antibodies in North America and shares profits and losses with I-Mab. Both agreements are in arbitration and the hearing was held in February 2022.



## Investment Highlight #3: Product Development Platform (PDP) of CRO-Independent Clinical Development and U.S. Commercialization Experience

- Eliminates the “fee-for-service and monthly fee” structure of CRO reimbursement that isn’t aligned with biopharma’s goals of low cost, rapid and high-quality clinical trials

- TRACON PDP is built to deliver clinical results rapidly in U.S./E.U. and provide opportunities for U.S. commercialization

- Drug development solution with strong collaboration alignment available for multiple therapeutic areas

- Proven ability to leverage PDP via business development sourced pipeline

1. Subcutaneous PD-L1 antibody envalfolimab from **3D Medicines** and **Alphamab Oncology**
2. CTLA-4 antibody from **Eucure Biopharma**, a division of **Biocytogen**
3. Prostate cancer asset from **Johnson & Johnson**<sup>1</sup>
4. CD73 antibody from **I-Mab**
5. Bispecific antibody collaboration with **I-Mab**

- Actively sourcing additional clinical stage assets for development

CHARLES THEUER M.D., Ph.D.  
WITH BONNE ADAMS, MARK WIGGINS, AND SCOTT BROWN

# UNNECESSARY EXPENSE



An **ANTIDOTE** for the  
**BILLION DOLLAR DRUG PROBLEM**

ForbesBooks



1: License was terminated by TRACON and assets have been returned to Janssen.

## Multiple Aligned Deal Structures Enabled by TRACON's PDP

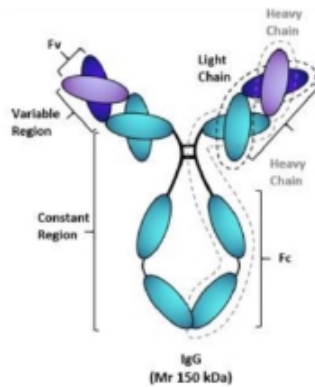
**Profit Share:** TRACON secures U.S. commercial rights, takes on clinical risk and cost, commercializes in the U.S. and shares profits (examples: 3D/Alphamab and Eucure collaborations)

**Pay for Performance:** TRACON performs clinical trials at a pre-negotiated fixed cost per patient and is paid upon accrual, and shares in product revenues (example: J & J collaboration)

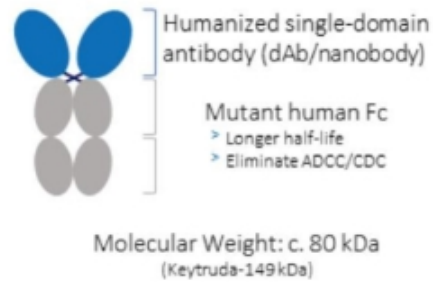
**Franchise:** TRACON receives payments to teach partner how to perform CRO-independent trials at reduced cost

# Envafolelimab – World's First Approved SubQ Dosed PD-(L)1

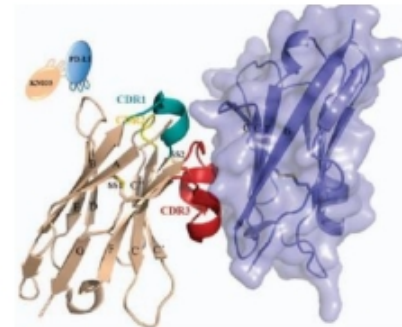
## Traditional Ab



## Envafolelimab



## Crystal Structure of Envafolelimab/PDL1



- Single Domain Antibody - structure of approved product Cablivi (Ablynx/Sanofi), which is also given subcutaneously
- Stable at room temperature for six months allows rapid low volume subcutaneous injection without an adjuvant (i.e., no need for hyaluronidase)
- High yield (> 7 g/L) and low cost of production by Alphamab Oncology (HKSE: 9966 Alphamab Oncology)

## All U.S. approved PD-(L)1 Antibodies are Delivered via IV Infusion



**KEYTRUDA<sup>®</sup>**  
(pembrolizumab) injection 100 mg

\$14.2B 2021 sales



Bristol-Myers Squibb

**OPDIVO<sup>®</sup>**  
(nivolumab)

\$7.6B 2021 sales

**REGENERON**

**LIBTAYO<sup>®</sup>**  
(cemiplimab-rwlc)  
injection 350 mg

\$306M 2021 sales



**BAVENCIO<sup>®</sup>**  
avelumab 800 mg

\$440M run rate



**TECENTRIQ<sup>®</sup>**  
atezolizumab  
injection 1200 mg

\$3.4B run rate

AstraZeneca

**IMFINZI<sup>®</sup>**  
durvalumab  
injection 1000 mg

\$2.4B 2021 sales



**JEMPERLI**

Approved late 2021

**TRACON**  
THERAPEUTICS

### IV Infusion

#### Disadvantages:

- Time Consuming and Uncomfortable
- Risk of Infusion Reactions



**ENVAFOLIMAB**  
Subcutaneous  
PD-L1

### Subcutaneous

#### Injection Advantages:








- Fast and Easy
- No risk of Infusion Reactions

## Envafolimab Rapid SubQ Administration: Potential Best-in-Class Profile



- Envafolimab, much improved subcutaneous dosing
  - Small injection volume: < 2 mL
  - Infrequent injection site reactions in clinical trials to date
  - Fast injection: in seconds
  - Stable at room temperature for months
  - Potential for development as a combination therapy

# Envafohimab Global Clinical Development Summary: Approved in China and Dosed to > 1,000 Cancer Patients

Development Country	Pre-Clinical	Phase 1	Phase 1b	Phase 2	Registrational (Phase 2/3)
	Sarcoma Subtypes of UPS/MFS				
	Pan-cancer (>15 solid tumors) with MSI-H/dMMR <i>Monotherapy – Single-arm, ORR - 2L/3L</i>				
	Biliary Tract Cancer (BTC) <i>Combo with chemo – Open-labeled, randomized, two-arm parallel, OS – 1L</i>				
	Gastric Cancer (GC) <i>Combo with chemo – Single-arm, exploratory – 1L</i>				
	Phase 1 <i>Monotherapy – Safety and efficacy</i>				
	Phase 1 <i>Monotherapy – Safety and efficacy</i>				
	Phase 1 <i>Monotherapy – Safety and efficacy</i>				

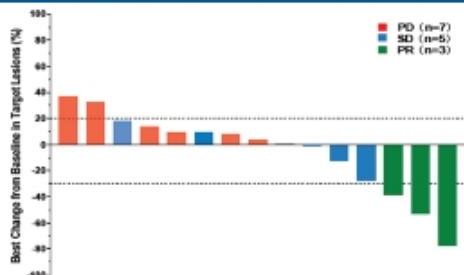
- Approved in microsatellite instability-high/mismatch repair-deficient (MSI-H/dMMR) cancer in China
- Being studied in multiple pivotal trials including ENVASARC

# Envafoimab – Safety, PK and Efficacy in Phase 1

## Highlights

- Safety profile in clinical studies to date similar to approved PD-(L)1 therapies, with elevated transaminases (mainly grade 1 or grade 2) being among the most common adverse events
- Has been dosed up to every 4 weeks. RECIST objective response rates (ORR) in three Phase 1 trials >15% across all dose levels and solid tumors
- **Confirmed ORR in Alveolar Soft Part Sarcoma (ASPS) of 40% (2/5 patients, both durable responses beyond 6 months) similar to Tecentriq confirmed ORR in ASPS (16/43 patients, 37%)<sup>1</sup>**

## Envafoimab Dose Escalation Study in China

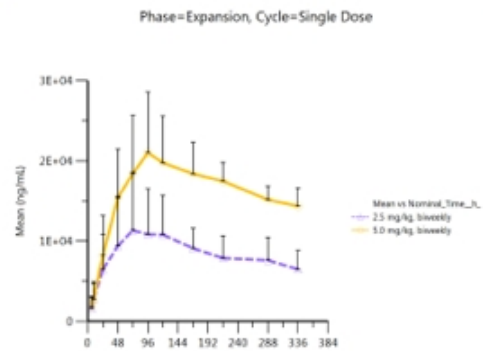


ASCO 2019 presentations: Xu J et al; Shimizu T et al; ESMO 2018 presentation: Papadopoulos et al  
CTOS 2018 presentation: Coyne et al.

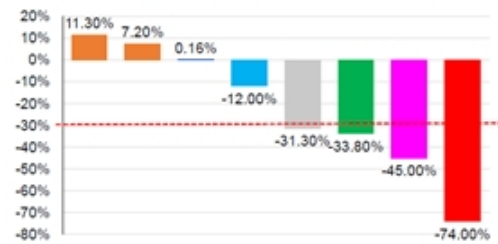


<sup>1</sup>: Data from Phase 1 trial in China conducted by 3D Medicines

## Envafoimab Dose Escalation Study in Japan



## Envafoimab Dose Escalation Study in US



## Envafohimab Efficacy in Pivotal Trial in MSI-H/dMMR Cancer Patients Similar to Opdivo and Keytruda Trials

- Envafohimab was approved in China in November 2021 in patients with advanced microsatellite instability-high/mismatch repair-deficient (MSI-H/dMMR) cancer
- Objective response rate (ORR) by blinded independent radiographic review of 44.7%, including 12 (11.7%) cases of complete response with duration of response at 12 months of > 90%.
- Confirmed ORR in MSI-H/dMMR colorectal patients who failed fluoropyrimidine, oxaliplatin and irinotecan is nearly identical to ORR reported for Opdivo and Keytruda in separate trials in that patient population
- Safety profile similar to other PD-(L)1 antibodies but without infusion reactions; no cases of colitis or pneumonitis were reported

	Envafohimab	Opdivo (CHECKMATE-142)	Keytruda (KEYNOTE-164)
Indication	MSI-H/dMMR colorectal cancer that progressed following treatment with fluoropyrimidine, oxaliplatin and irinotecan		
Sample Size	41	53	61
ORR by independent radiographic review	32%	28%	33%
Duration of Response ≥ 12 months	75%	40%	NA



- Address a high unmet medical need
  - Low hurdle for efficacy and safety in refractory disease: standard of care treatment Votrient® (pazopanib) has 4% response rate and Black Box Warning for fatal liver toxicity
  - Opportunities for expansion into first line and neoadjuvant treatment settings
- Most conveniently administered checkpoint inhibitor (SubQ)
  - Convenient for patients and physicians, can be rapidly administered in-office
  - Avoids need for IV infusion and risk of infusion reactions
  - Cost to the insurers expected at parity to gold-standard IV administered products

## High Unmet Need in Undifferentiated Pleomorphic Sarcoma (UPS) and High-grade Myxofibrosarcoma (MFS)

- Common soft tissue sarcomas (formerly called malignant fibrous histiocytoma or MFH)
  - ~2,000 cases of UPS in the US annually (Western world incidence: 0.8-1.0/100,000)
  - Myxofibrosarcoma (MFS) half as common as UPS with ~1,000 cases annually in US
- **First line chemotherapy with doxorubicin is typical with objective response rate of ~17%**
- **Only approved agent for refractory UPS/MFS, Votrient, has 4% objective response rate**
- Advanced or metastatic UPS/MFS has 5-year overall survival of < 5%

### PD-(L)1 Could Address Unmet Need in Sarcoma

- ASCO 2019: Keytruda, a PD-1 inhibitor, demonstrated a 23% objective response rate in refractory UPS/MFS
- ASCO 2020: combination of Opdivo, a PD-1 inhibitor, and Yervoy, a CTLA-4 inhibitor, tripled the objective response rate to 29% in refractory UPS/MFS compared to Opdivo alone
- **To our knowledge, no company is currently conducting a pivotal trial in sarcoma with a PD-(L)1**
- An approved subcutaneous PD-(L)1 could have the potential advantage of physician preference and market access/reimbursement in sarcoma

## Accelerated Approvals of PD-(L)1 Treatments in Refractory Solid Tumors have been Based on ~15% Objective Response Rates

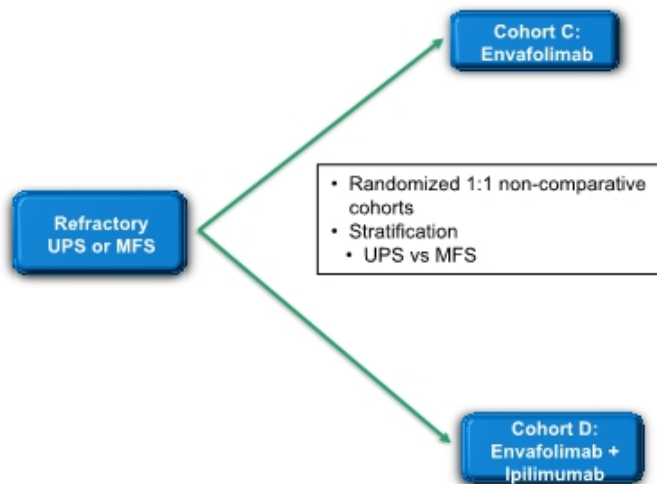
- FDA has been supportive of therapeutics that address unmet needs, with the bar for accelerated approval being ~ 15% response rate in those indications
  - Keytruda was approved in refractory gastric cancer with response rate of 13% and in refractory cervical cancer with response rate of 14%
  - Tecentriq was approved in refractory urothelial cancer with response rate of 15%
  - Opdivo was approved in refractory small cell lung cancer with response rate of 12%

	PD-L1+ Gastric (Keytruda)	Urothelial (Tecentriq)	Small Cell Lung (Opdivo)	PD-L1+ Cervical (Keytruda)
<b>ORR</b>	<b>13%</b>	<b>15%</b>	<b>12%</b>	<b>14%</b>
<b>CDX in label</b>	<b>Yes</b>	<b>No</b>	<b>No</b>	<b>Yes</b>

- Tazemetostat was approved in January 2020 in epithelioid sarcoma with response rate of 11% and 15% in separate trials

# ENVASARC Pivotal Trial Design

Envafolelimab (cohort C & D): 600 mg Q3weeks SubQ  
Ipilimumab (cohort D only): 1 mg/kg Q3weeks i.v. x 4

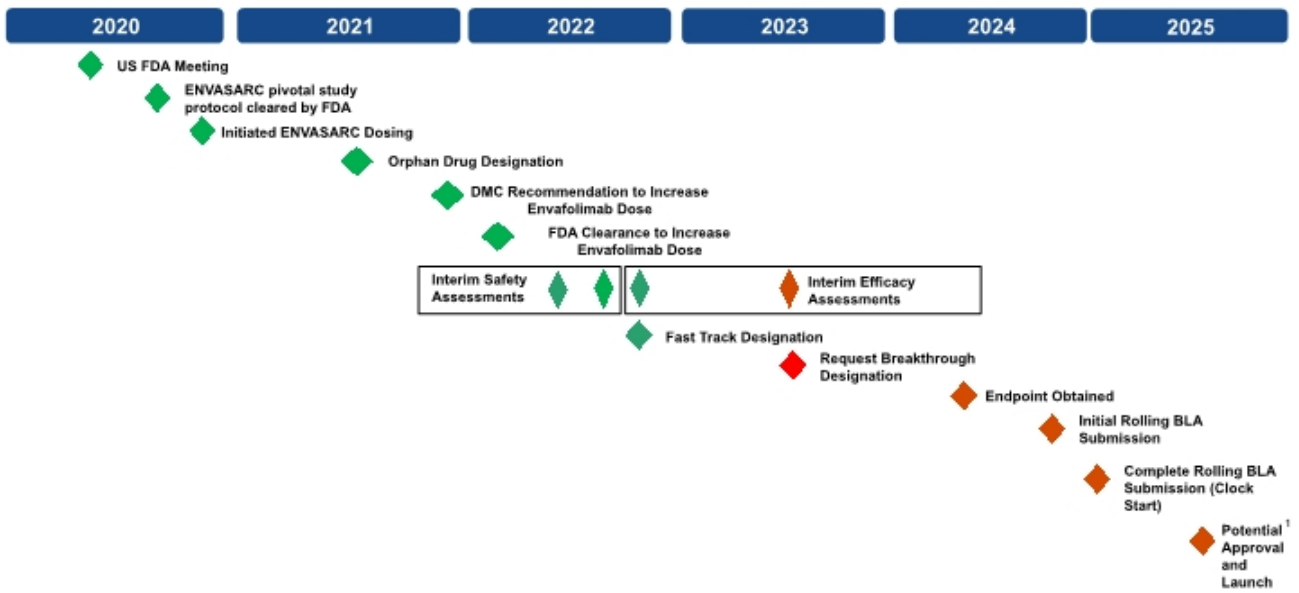


- **Primary Endpoint:** ORR by blinded central review; 9/80 responses in either cohort (11.25% ORR) will produce a lower bound of the 95% confidence interval that excludes the documented Votrient ORR of 4%
- Key Secondary Endpoint: DOR and safety
- Key eligibility
  - Age  $\geq 12$
  - Measurable disease by RECIST 1.1
  - No prior treatment with immune therapy
  - No more than 2 prior lines of treatment
  - ECOG PS 0-1
- Independent blinded central review
- Futility rules: 0/18 or  $\leq 2/46$  ORR

## Positive ENVASARC DMC Review in December 2022

- The DMC reviewed interim safety and efficacy data from 18 patients enrolled into each cohort who completed a minimum of 12 weeks of efficacy evaluations (two on-treatment scans)
- Double-digit ORR assessed by blinded independent central review observed in each cohort that more than satisfied the prespecified futility rule
- Envafolelimab monotherapy and in combination with Yervoy was well tolerated, with only a single related serious adverse event reported in 36 patients
- DMC recommended continued enrollment as planned; enrollment is ahead of schedule; next interim analysis expected in mid-2023 with full accrual expected before end of 2023

# Envafolimab Development Plan in Sarcoma

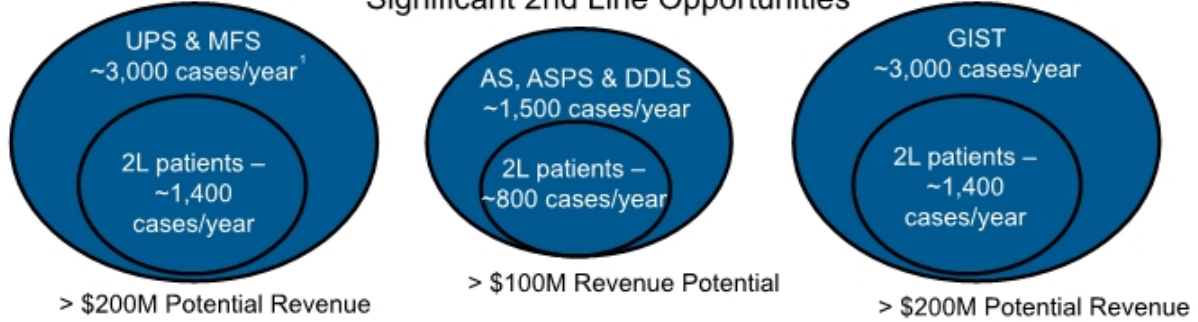


## Envafolimab Target Product Profile:

Dual approval based on single agent ORR of ~15% and combination agent ORR of ~30% in refractory UPS/MFS with majority of patients having duration of response > 6 months, with a similar or superior safety profile compared to other approved PD-(L)1 therapies. Note Opdivo is approved as a single agent and in combination with Yervoy in MSI-H cancer.

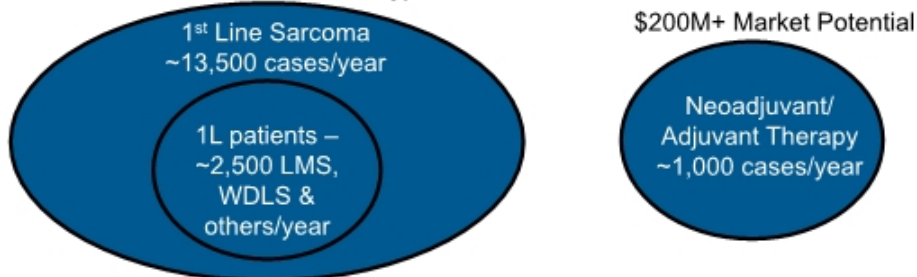
## U.S. Market Size in Sarcoma Estimated at >\$1B Assuming Parity Pricing

### Significant 2nd Line Opportunities



### Label Expansion Opportunities – 1<sup>st</sup> Line + Adjuvant

\$400M Increase in Potential  
Revenue in Sarcoma Subtypes



UPS – Undifferentiated pleomorphic sarcoma; MFS – myxofibrosarcoma; AS – Angiosarcoma; ASPS – Alveolar soft part sarcoma; DDLS – Dedifferentiated Liposarcoma; GIST – Gastrointestinal stromal tumors; WDLS – Well Differentiated Liposarcoma; LMS – leiomyosarcoma  
1: UPS estimate from Orpha.net (.8 cases per 100K); unless otherwise noted, all figures are TRACON estimates

## Envafolimab License with 3D/Alphamab in N. America

- TRACON to conduct and bear costs of clinical trials in Sarcoma in North America
- 3D/Alphamab manufacture Envafolimab for TRACON at pre-negotiated prices
- TRACON to commercialize Envafolimab in sarcoma in North America
  - TRACON will lead commercialization if first launch in U.S. is in Sarcoma
  - TRACON has option to co-market if first launch is by 3D Medicines, or approval occurs in a non-orphan indication after TRACON's approval in Sarcoma
- If TRACON books sales in Sarcoma, we owe double digit royalties to 3D/Alphamab ranging from teens to mid-double digits.
- If 3D/Alphamab books sales they will owe TRACON double digit royalties ranging from teens to mid-double digits if TRACON does not co-market, and a 50% royalty on Sarcoma sales if TRACON elects to co-market
- 3D/Alphamab can reacquire Envafolimab if the product is sold to a third party after TRACON and 3D/Alphamab negotiate fair compensation for TRACON



# Envafohimab as a Potential Backbone Therapy for Future Combinations

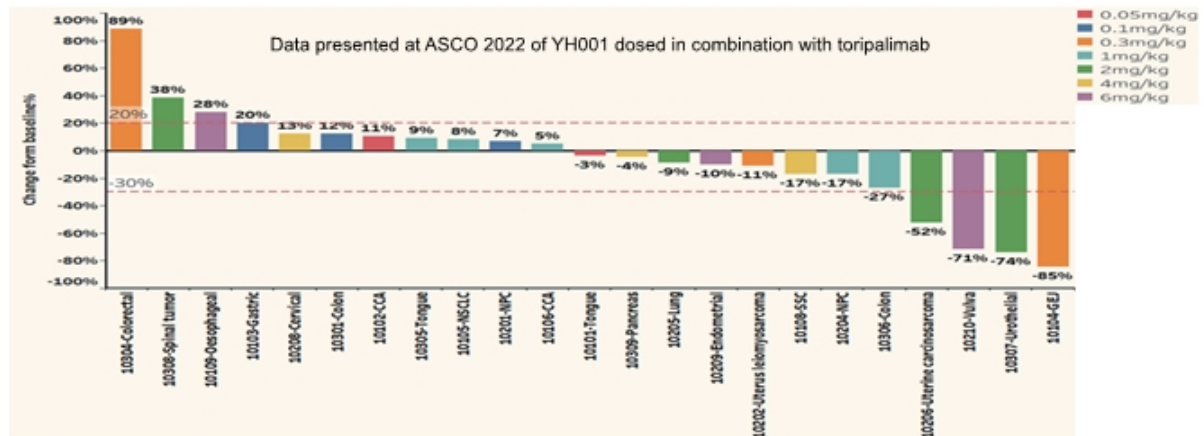
Trials by target - PD-(L)1 Combinations



Source: [www.cancerresearch.org](http://www.cancerresearch.org)

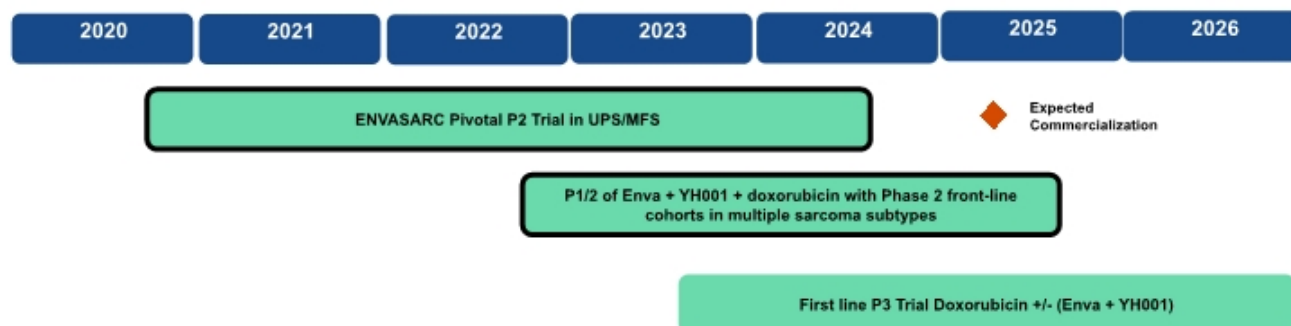
## YH001 Phase 1 trials

- Single agent dose escalation completed in China
- Dose escalation with PD-1 antibody toripalimab completed in Australia
- Phase 1/2 trial of YH001 + envafolimab + doxorubicin for first-line treatment of sarcoma patients, initiated dosing in 2022



Among 23 patients that had image tumor assessments available, four achieved partial response by RECIST, including in one patient with urothelial cancer who had failed prior treatment with a PD-1 antibody, and nine had stable disease, for an ORR of 17.4% and disease control rate of 56.5%

# Envafolelimab and YH001 Development Plan in Sarcoma



## Envafolelimab and YH001 Development in Sarcoma:

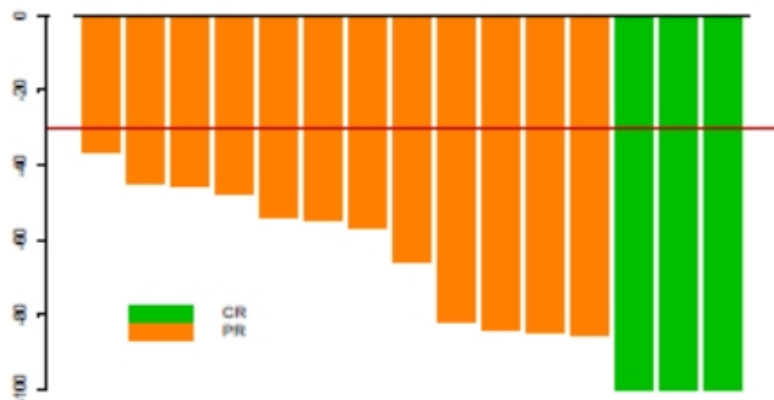
Initial approval of envafolelimab expected in refractory UPS/MFS through the ENVASARC trial, followed by approval in first line sarcoma (including UPS/MFS and other subtypes) with YH001 and doxorubicin based on randomized controlled Phase 3 trial.

## YH001 License Terms with Eucure in North America

- License for indication of sarcoma and three additional named indications (renal cell carcinoma, Kras mutant lung cancer and colorectal cancer) as well as three substitution indications (endometrial cancer, bladder cancer and melanoma)
- TRACON opt-in opportunity for low single-digit million dollars at Eucure's discretion for all North American indications
- TRACON to conduct and bear costs of clinical trials in North America
- Eucure to manufacture Envafolimab and sell to TRACON at pre-negotiated prices
- TRACON to commercialize Envafolimab in noted indications in North America
- TRACON will owe double digit royalties to Eucure ranging from low double digits to mid-double digits in first year of launch and from mid-twenties to mid-double digits thereafter.

## DNA Repair Inhibitor TRC102 Improves Response Rate to Chemoradiation in Advanced Localized Lung Cancer

Data reported at ASCO 2020



TRC102 + Alimta/cisplatin  
and radiation in Advanced  
Localized Lung Cancer

**100% Response rate –**  
**Of 15 evaluable patients:**  
**3 had CR (20%)**  
**12 had PR (80%)**  
**2-year PFS rate was**  
**49%**

In 2022, NCI initiated first line randomized Phase 2 trial in advanced localized lung cancer of chemoradiation +/- TRC102 with Imfinzi maintenance; Data expected in 2024

## I-Mab Corporate Collaboration: CD73 antibody TJ4309

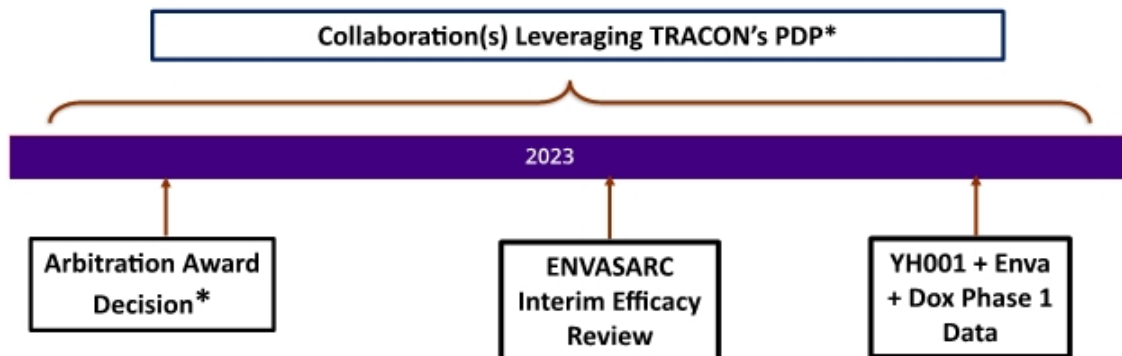
	2019	2020	2021
TJ4309	Phase 1 Solid Tumors with Tecentriq		

- TJ4309 Phase 1 data presented at ASCO:
  - TJ4309 was safe and well-tolerated as a monotherapy and in combination therapy with Tecentriq. No dose limiting toxicity was observed and the MTD was not reached.
  - Full saturation of circulating and cell-bound CD73 achieved at doses  $\geq 10$  mg/kg.
  - Linear PK profile at the doses  $\geq 10$  mg/kg following a single dose and supports Q3W dosing.
  - Evidence of clinical activity following treatment with TJ4309 and Tecentriq.
- TRACON is entitled to revenue sharing of royalty and non-royalty consideration received by I-Mab for territories outside China, ranging from a high-single digit to mid-teen % of non-royalty consideration as well as double digit % of royalty consideration
- I-Mab has indicated their desire to exercise their option to terminate the TJ4309 license following completion of the Phase 1 trial for a payment to TRACON of \$9M

## I-Mab Disputes and Arbitration

- I-Mab commenced arbitration in June 2020, after TRACON invoked contractual dispute resolution provisions asserting that I-Mab had breached its contractual obligations concerning the TJ4309 and Bispecific Antibody Agreements entered into in November 2018.
- TRACON filed counterclaims in the arbitration seeking to recover over \$200 million in damages from I-Mab based on the alleged breaches. Under the applicable rules of the arbitration the prevailing party may also be awarded attorneys' fees at the Tribunal's discretion.
- In February 2022 arguments for alleged breaches of both agreements with I-Mab were heard before an International Chamber of Commerce (ICC) arbitration tribunal under New York law, and the final post-hearing briefs were submitted to the Tribunal in May 2022.
- On June 2, the International Court of Arbitration of the ICC notified us to expect a final decision by September 30<sup>th</sup>. In September, the ICC notified us to expect a final decision by November 30<sup>th</sup>.
- On November 8, the Tribunal invited the parties to submit an additional, limited briefing on two discrete issues by December 9. Following that submission, the parties are to agree on a schedule for their respective cost submissions. The Tribunal did not indicate when it expects to render its award; however, the Tribunal did note they are far along in their deliberations and preparation of a final award, and we expect the Tribunal to provide their final award in 1Q 2023.
- TRACON continues to meet our obligations under the terms of both agreements.
- In December 2022, TRACON entered into an up to \$30M non-recourse non-dilutive funding agreement related to the arbitration. \$3.5M was funded at close and the remainder will be available subject to the award exceeding a threshold and other conditions.

## Expected Key 2023 Milestones



\* Non-dilutive Capitalization Opportunities



## Financial Overview (as of December 31, 2022)

Ticker	TCN (NASDAQ)
Cash and Cash Equivalents	\$17.4 million*
Debt – Outstanding Principal	\$10.0 million*
Common Shares O/S	23.1 million
Cash Runway	Mid-2023**
Covering Analysts	<ol style="list-style-type: none"> <li>1. Bert Hazlett (BTIG)</li> <li>2. Ed White (H.C. Wainwright)</li> <li>3. Jason McCarthy (Maxim)</li> <li>4. Soumit Roy (JonesTrading)</li> <li>5. Matt Cross (AGP)</li> <li>6. Joel Beatty (Baird)</li> </ol>

\*Debt was paid in full on January 3, 2023. We have not yet completed our quarter-end financial close process for the quarter ended December 31, 2022. This estimate of our cash and cash equivalents as of December 31, 2022 is preliminary, has not been audited and is subject to change upon completion of our financial statement closing procedures. Additional information and disclosure would be required for a more complete understanding of our financial position and results of operations as of December 31, 2022.

\*\*Based on management's current expectations and beliefs.



# Investment Highlight #1: Envafolimab, a Potential Best-in-Class Checkpoint Inhibitor in Pivotal Trial in Unmet Need Indication

## ENVAFOLIMAB

**Potential for Near-term U.S. Commercialization of the 1<sup>st</sup> Approved PD-(L)1 Subcutaneous Checkpoint Inhibitor**

Rapid low volume subcutaneous injection without an adjuvant that is more convenient, less invasive and safer than IV therapy



(1) Assuming successful pivotal study

(2) Third party estimate sponsored by TRACON

### Rapid Execution

ENVASARC pivotal trial began dosing in sarcoma in 4Q 2020 following successful FDA meeting

### Orphan Drug and Fast Track Designation in Sarcoma

### Fast to Market Strategy

Expect ENVASARC interim data in 2023, final data and U.S. BLA in 2024 and launch in 2025<sup>(1)</sup>

### Financial Upside

Peak U.S. annual revenue estimated at >\$300M in initial indications using parity pricing to approved PD-(L)1 products<sup>(2)</sup>  
ENVASARC pivotal trial cost estimated at <\$25M through TRACON Product Development Platform.

