

# Corporate Presentation

**May 2024**

*Nasdaq: TSBX*

Non-Confidential



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## OUR MISSION

Profoundly transform the treatment paradigm for patients with a broad range of **solid tumors** with **next-generation TIL therapies** that overcome the limitations of current treatment options



Mike Mielnik  
Senior Scientist, Turnstone Biologics

# Solid Tumors Represent a Serious Unmet Medical Need

*Approximately 90% of all new cancers per year are solid tumors*

## In the U.S. Each Year

**1.6M**

new cancer  
patients<sup>1</sup>

**500K**

deaths with low  
long-term survival<sup>1</sup>

**90%+**

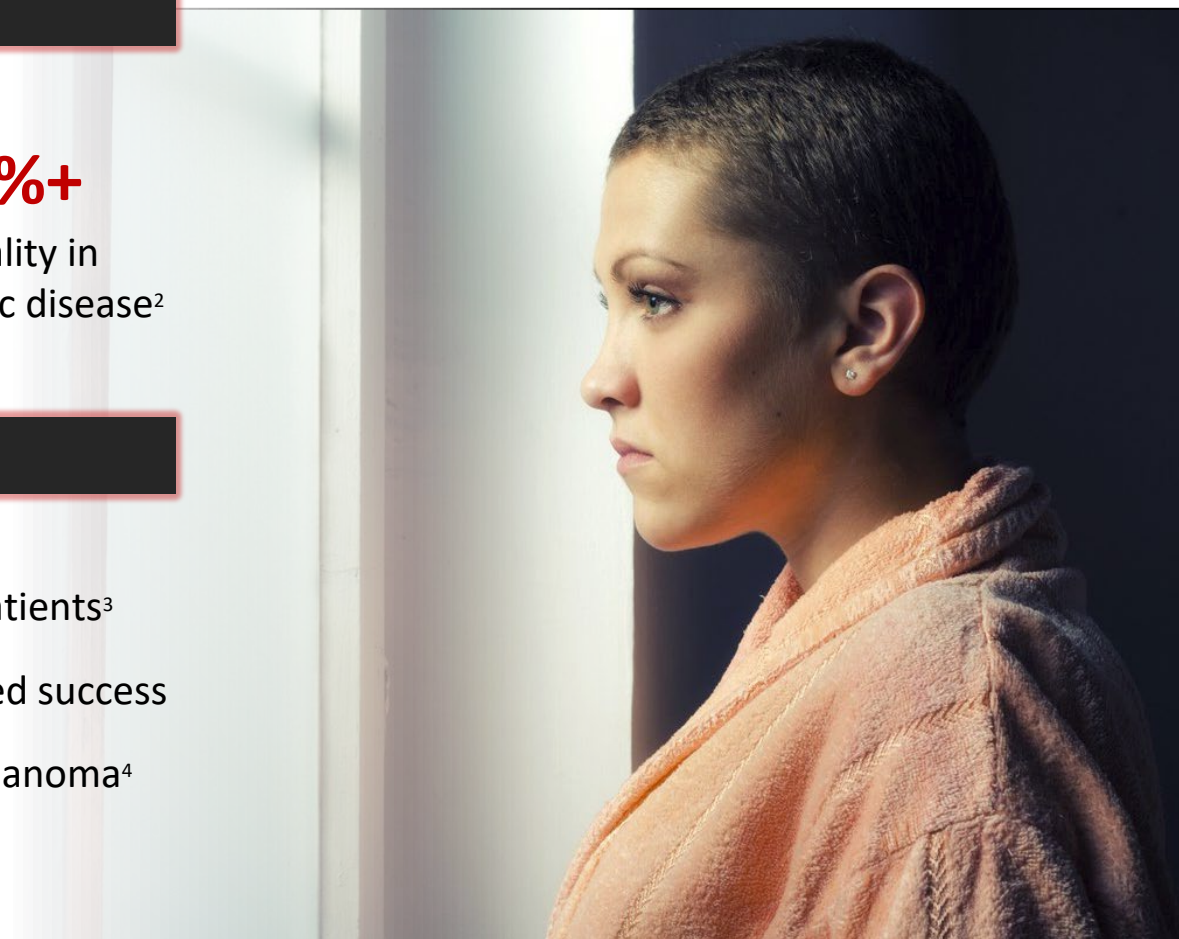
mortality in  
metastatic disease<sup>2</sup>

## New Therapeutic Options Urgently Needed

Checkpoint inhibitors only benefit a fraction of cancer patients<sup>3</sup>

Targeted and other cell therapies have shown only limited success

One FDA approved TIL therapy and only in advanced melanoma<sup>4</sup>



<sup>1</sup>National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER), accessed March 2024; <sup>2</sup>Cancer Metastasis: Guan X. Cancer Metastases: Challenges and Opportunities. Acta Pharm Sin B. 2015 Sep;5(5):402-18.;

<sup>3</sup>Haslam A, Prasad V. Estimation of the Percentage of US Patients With Cancer Who Are Eligible for and Respond to Checkpoint Inhibitor Immunotherapy Drugs. JAMA Netw Open. 2019 May 3;2(5):e192535.;

<sup>4</sup>United States Food and Drug Administration (US FDA) approval granted on 02/16/2024; [News release](#)



# Turnstone is Tackling Solid Tumors of Greatest Need

*Our focus is on CRC, HNSCC, uveal melanoma, breast cancer, and cutaneous melanoma*

## Indication Spotlight: Colorectal Cancer (CRC)

**2<sup>nd</sup> Leading Cause of  
U.S. Cancer Deaths<sup>1</sup>**

**3<sup>rd</sup>** most commonly  
diagnosed cancer<sup>2</sup>

**153K** expected new  
cases this year<sup>3</sup>

**53K** number of deaths  
expected in 2024<sup>4</sup>

**Difficult-To-Treat Tumor  
Unresponsive To Most  
Immune-Based Therapies**

Immunologically “cold”  
tumor characterized by  
low tumor mutational  
burden (TMB)

**TURNSTONE**  
BIOLOGICS

We believe the key to  
overcoming challenges of  
CRC and other “cold” tumors  
is large numbers of on-target  
tumor-reactive T cells which is  
the foundation for Turnstone’s  
approach of **Selected TIL therapy**

<sup>1</sup>American Cancer Society. Cancer Facts & Figures 2024; <sup>2</sup>CA: A Cancer Journal for Clinicians – Colorectal Cancer Statistics, 2023 – DOI: 10.3322/caac.21772;

<sup>3</sup>, <sup>4</sup>National Cancer Institute’s Surveillance, Epidemiology, and End Results (SEER), accessed March 2024

# Turnstone is Pioneering Advancements in Selected TIL Therapy

*Next-generation therapy designed to treat and cure solid tumors*



TILs have been recently **approved by the FDA\*** for the treatment of cutaneous melanoma



**Differentiated approach** centered around **tumor-reactive T cell selection** (Selected TILs)



**Targeting underserved solid tumor patient populations**, including CRC, HNSCC, uveal melanoma and breast cancer



Lead asset, **TIDAL-01**, being evaluated in multiple Phase 1 studies with initial **clinical data expected in mid-2024**

# Turnstone Executive Team

*Proven experience across all areas and stages of drug development*



**Sammy Farah, MBA, PhD**  
Chief Executive Officer

- 20+ years of scientific, business and executive management experience in biotech industry
- Held senior positions at **Merck**, **Immune Design**, and **Synthetic Genomics**
- Previously at **Versant Ventures** specializing in biotechnology investing and new company formation



**Stewart Abbot, PhD**  
Chief Scientific Officer

- 20+ years of R&D experience in cell-based and immuno-oncology products
- Former CSO and COO at **Adicet Bio**, responsible for R&D activities for allogeneic gamma delta T cell therapies
- Previously CDO at **Fate Therapeutics**, developing cellular immunotherapies



**Saryah Azmat**  
Chief Business Officer

- 10+ years of experience in biopharma business development, corporate strategy and capital formation
- Former Global Lead for Oncology Search & Evaluation at **Bristol-Myers Squibb**, executing over 15 major transactions from preclinical to clinical development



**Mike Burgess, MBChB, PhD**  
Interim Chief Medical Officer

- 20+ years experience building and leading clinical development
- Led strategy and execution of translational medicine across all therapeutic areas as SVP of Cardiovascular, Fibrosis and Immunoscience Development at **Bristol-Myers Squibb**
- Previous Global Head of Oncology Research and Early Development at **Roche**



**Vijay Chiruvolu, MBA, PhD**  
Interim Chief Technology Officer

- 27+ years of manufacturing and process development experience
- Served as SVP of Global Process Development-Cell Therapy at **Kite Pharma/Gilead Sciences**, responsible for the CMC/process development leading to regulatory approval of two cell therapy products, Yescarta and Tecartus



**Venkat Ramanan, PhD**  
Chief Financial Officer

- 20+ years of biopharma finance and operations experience
- Joined from **Seagen** where he led the Finance function as the company launched several products, expanded global footprint and executed multiple strategic transactions



# Turnstone External Network

*Supported by prominent scientific and corporate advisors and collaborators*

## Key Collaborators



**James Mulé, PhD**

Associate Center Director of Translational Science  
Moffitt Cancer Center



**Steven A. Rosenberg, MD, PhD**

Chief of Surgery Branch  
National Cancer Institute



**Simon Turcotte, MD, MSc**

Associate Professor of Surgery;  
Lead of Adoptive T Cell Cancer Immunotherapy Program,  
University of Montreal Hospital Research Centre (CRCHUM)

## Distinguished Advisors



**Malcolm Brenner, MD, PhD**

Professor, Center for Cell and Gene Therapy  
Baylor College of Medicine



**Thomas Dubensky Jr., PhD**

Founder and Advisor  
Tempest Therapeutics



**Bernard Fox, PhD**

Chief, Laboratory of Molecular  
and Tumor Immunology  
Providence Cancer Institute



**Adrian Hill, PhD**

Director, The Jenner Institute  
University of Oxford



**Alan Melcher, PhD**

Team Leader  
Translational Immunology  
The Institute of Cancer Research



**Nicholas Restifo, MD**

Special Volunteer  
National Institutes of Health



**Robert Seder, MD**

Chief, Cellular Immunology Section  
Vaccine Research Center  
National Institutes of Health



**Eric Tran, PhD**

ACT Laboratory Lead  
Providence Cancer Institute



**Jeffrey S. Weber, MD, PhD**

Deputy Director, PCC;  
Co-Director, Melanoma  
Research Program  
NYU-Langone Cancer Center







**Tassos Gianakakos, MBA**

Former CEO  
MyoKardia



# Turnstone Pipeline

*Opportunity to address broad set of solid tumor patient populations*

Program		Product Overview	Key Indications	Preclinical	Phase 1	Phase 2	Phase 3	Next Anticipated Milestone
Selected TILs	TIDAL-01	Tumor-reactive Selected TILs	Breast cancer; CRC; HNSCC; Uveal melanoma				Initial clinical data in mid-2024	
			CRC; Cutaneous and non-cutaneous melanomas; HNSCC	Moffitt Collaboration* 				
		Combination with viral immunotherapy	Solid tumors				IND submission	
	TIDAL-02	Selected TILs with next-gen manufacturing and TIL quality enhancements	Solid tumors				IND submission	

\*Two concurrent investigator sponsored trials at Moffitt Cancer Center  
CRC = Colorectal cancer; HNSCC = Head and neck squamous cell carcinoma



# SELECTED TILs AND TIDAL-01

# Expanding the Frontiers of TIL Therapy

*Building upon first-to-market TIL therapy to deliver differentiated product with unique market opportunity*

First approval for a TIL therapy  
brings new option for solid tumors



Turnstone is developing the  
**Next-Generation of TIL Therapies**

- Amtagvi is the first and only FDA-approved TIL therapy, and the only T cell therapy for a solid tumor
- Amtagvi is a first-generation bulk TIL therapy approved to treat only advanced melanoma\*

Bulk TILs have **failed to show success** in most **solid tumors** outside melanoma

**Significant opportunity** for next-gen products

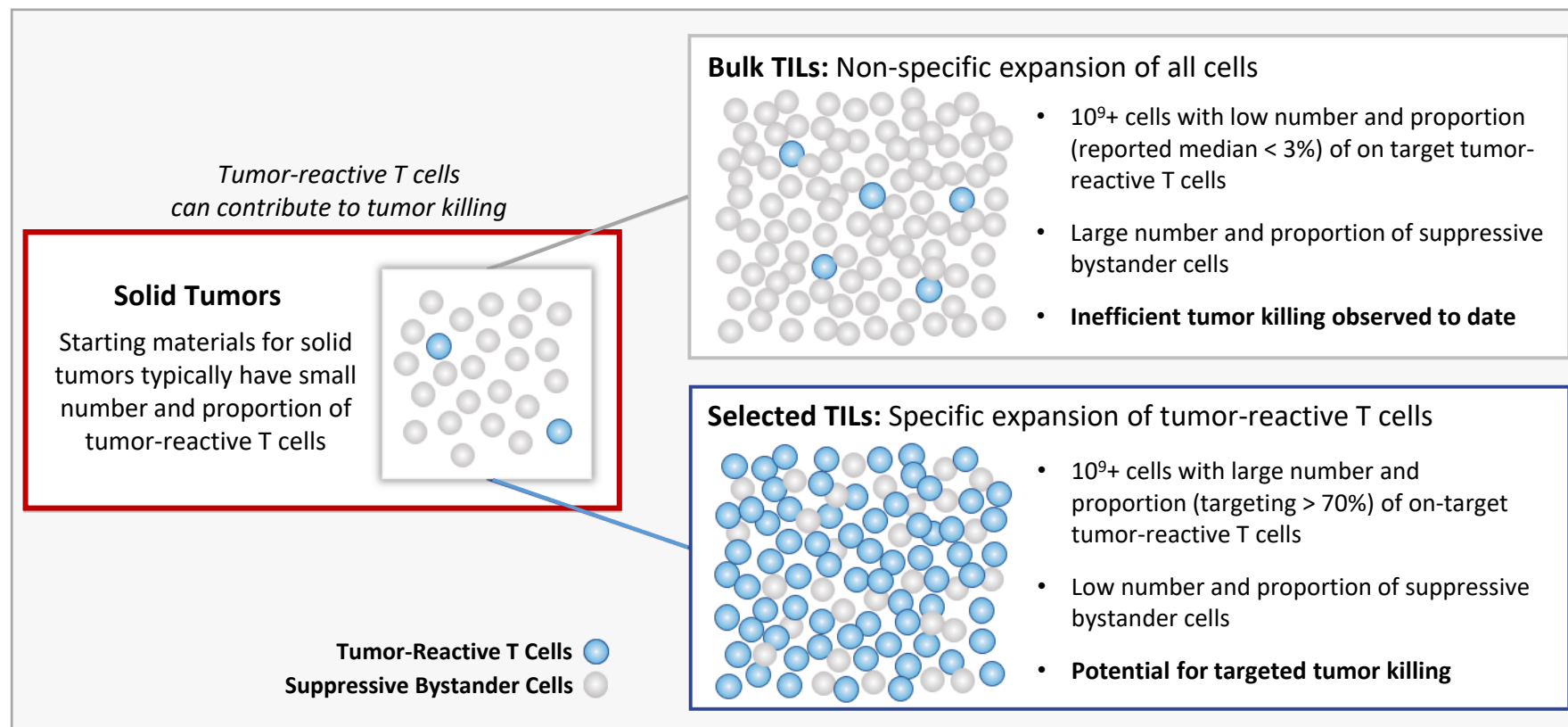
More **targeted and potent tumor killing** is a must

- Increasing total number of tumor-reactive T cells is key **area of differentiation**
- Academic studies provide early **clinical evidence** for selected TIL approach
- Potential to **broaden efficacy into additional solid tumors** with critical unmet need

# Selected TILs Have Potential for More Targeted Tumor Killing

## Selected TILs

- Next-generation TIL therapy based on **isolation, selection** and **expansion** of tumor-reactive T cells to improve product potency<sup>1</sup>
- Designed to address a broad range of solid tumor types



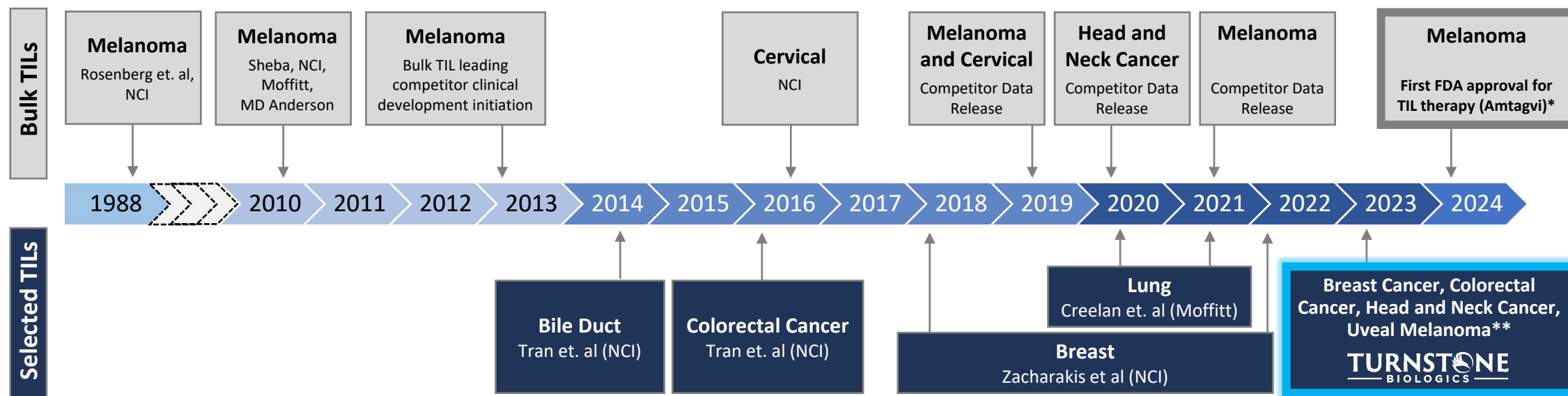
<sup>1</sup> We define potency as the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result



# Selected TILs Are Based on Advances from Academia

Early academics working on first-generation TILs led to development of a leading Bulk TIL company's current process

⇒ Success to date has been limited to melanoma



Recent academic data in next-generation TILs has provided early clinical evidence for next-generation selected TIL approach


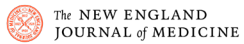


⇒ Objective responses extended to other major solid tumor types

# Clinical Validation of Selected TILs

Historical data from the NCI demonstrates limited evidence of benefit of Bulk TILs in epithelial malignancies

	Tumor Type	N	Response	Source
Bulk TILs	Various Solid Tumors (including Colorectal, Bile Duct, Pancreas, Breast, Gastric)	50+	No success	NCI – Rosenberg AACR 2020 / NCT01585428

Early academic selection strategies<sup>1</sup> deployed at the NCI have demonstrated clinical POC

	Tumor Type	N	Response	Source
Academic Selected TILs	Bile Duct (Cholangiocarcinoma)	1	1 PR	NCI - Tran et al; Science 2014 
	Colorectal Cancer	1	1 PR	NCI - Tran et al; NEJM 2016 
	Non-Small Cell Lung Cancer	7*	2 CRs, 1PR	Moffitt - Creelan et al; Nature Medicine 2021 
	Breast Cancer	6†	1 CR, 2 PRs	NCI - Zacharakis et al; JCO 2022 

\*7 patients received TIL product with confirmed tumor-specific reactivity out of 13 patients who were evaluable for clinical response

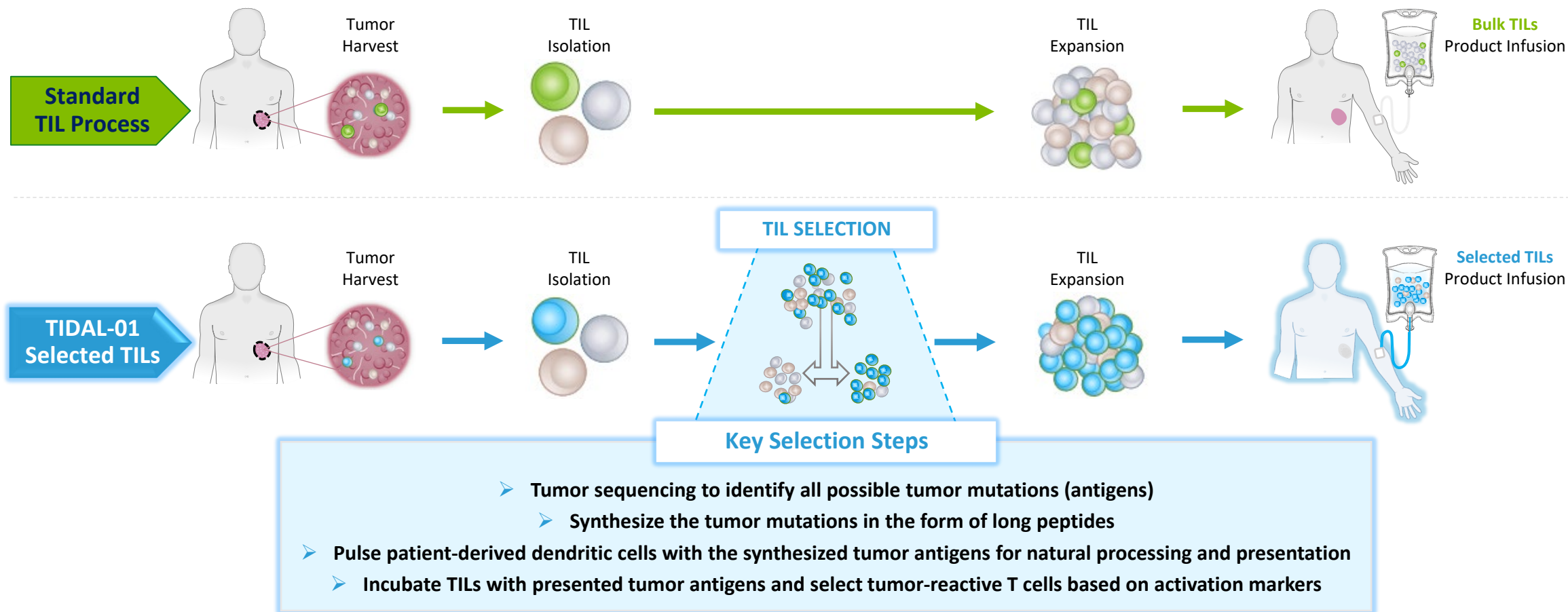
†6 patients enrolled on adoptive cell transfer protocol of enriched neoantigen-specific TIL out of 28 patients who contained TIL that recognized at least one immunogenic somatic mutation

<sup>1</sup> Early academic selection and enrichment strategies typically utilized fragment-based selection and expansion approaches. Following harvest and dissection of the tumor, small numbers of tumor fragments were placed into separate multi-well tissue culture dishes and cultured with the tumor or manufactured antigens. TIL populations that were activated by exposure to tumor antigens in culture would then be identified based on cytokine expression and/or T cell activation marker expression, and only those activated TIL populations would be expanded for use in the final product

# TIDAL-01 Process

*Designed to select a more potent population of T cells*

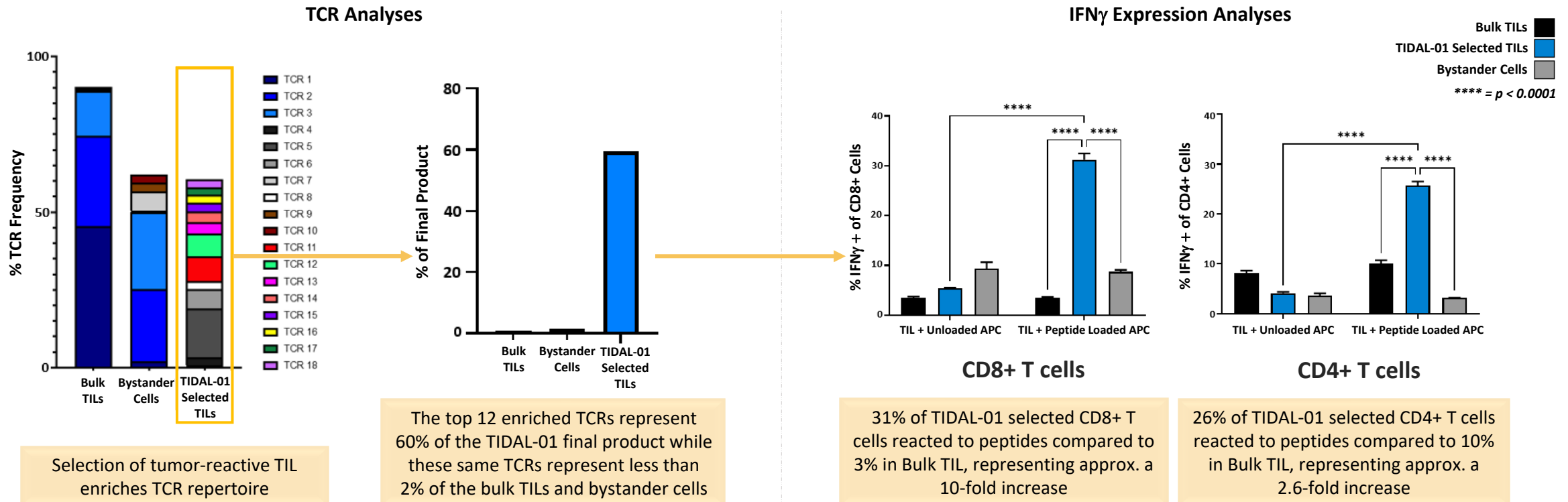
The TIDAL-01 process is similar to standard bulk TIL processes but includes a selection step designed to create a TIL product with a significantly higher proportion of tumor-reactive T cells for more effective tumor killing



# TIDAL-01 Designed to Select for Tumor-Reactive T Cells that are Typically Only Found in Very Low Levels in Bulk TILs

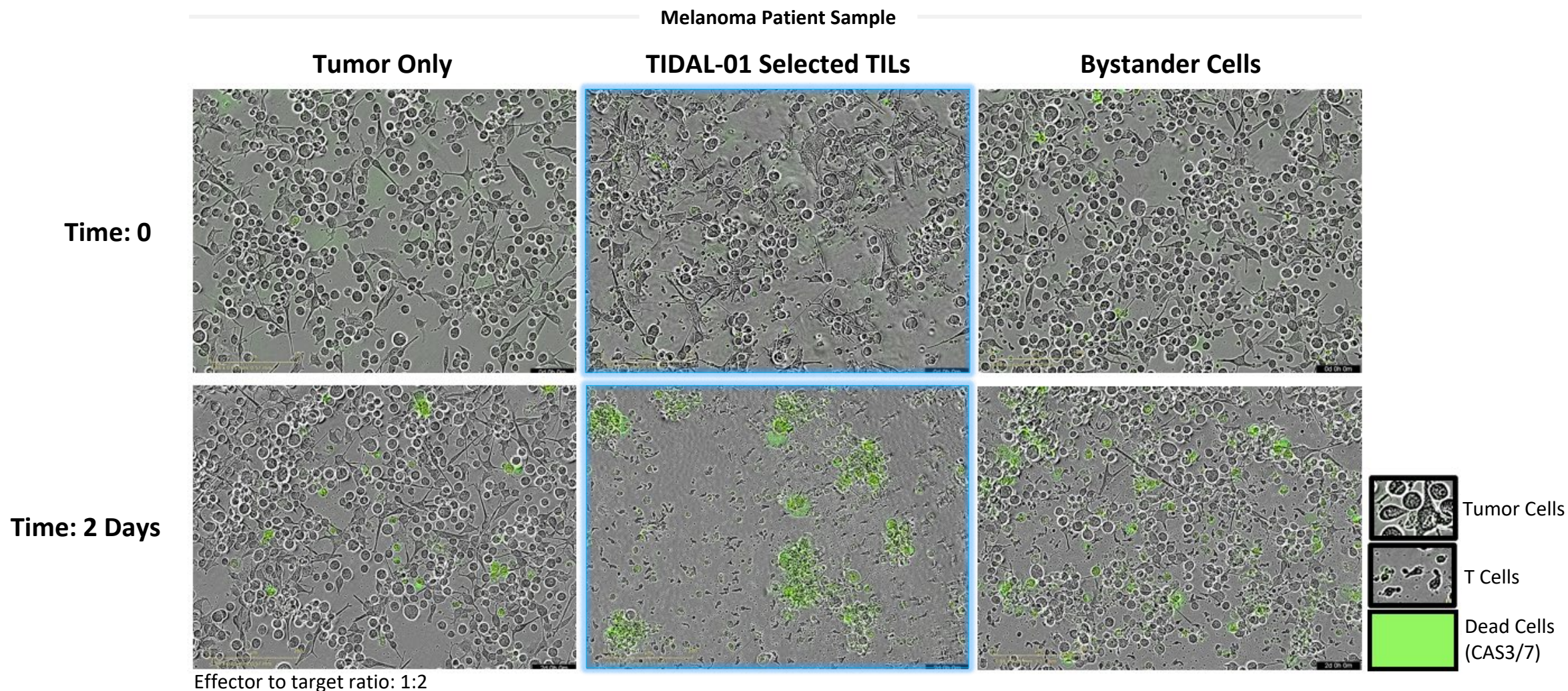
- TIDAL-01 product consists of diverse set of T cells with confirmed tumor-reactivity (TCRs)
- Selected tumor-reactive T cells are typically found in only very low frequencies in Bulk TILs
- These TCRs within Selected TILs deliver higher frequency of immunostimulatory cytokine expression in CD4+ and CD8+ T cells vs. Bulk TILs

## Colorectal Cancer Patient Sample





# TIDAL-01 Displays Higher Capacity to Kill Tumor Cells





# TIDAL-01 CLINICAL DEVELOPMENT

# TIDAL-01 Phase 1 Clinical Trials in Advanced Solid Tumors

## Phase 1 Study

Demonstrate the safety, biology, initial efficacy and manufacturing feasibility of TIDAL-01 in a Phase 1, first-in-human, non-randomized, open-label, single-dose study in patients with advanced solid tumors

## Design

**TIDAL-01 TIL viable cells:  $\geq 1 \times 10^9$**   
**High dose IL-2** (consistent with Bulk TIL doses)

### TIL Manufacturing



*\*a-PD1 combination in STARLING clinical trial and in HNSCC and CRC under Moffitt investigator-sponsored trials;  
Patients will also be receiving pembrolizumab as their anti-PD-(L)1 treatment two weeks after the TIDAL-01 infusion.  
Pembrolizumab will be dosed every three weeks until confirmed progressive disease or CR*

## Objectives

### Primary Objective:

- Safety and tolerability

### Key Secondary Objectives:

- Overall response rate (ORR)
- Duration of response (DoR)

# TIDAL-01 Phase 1 Study is Actively Enrolling Patients

## Structure



Turnstone sponsored trial (**STARLING**)  
enrolling across 10+ clinical sites

- Colorectal cancer (CRC)
- Head and neck cancer (HNSCC)
- Uveal melanoma
- Breast cancer



Two investigator-sponsored trials in  
collaboration with Moffitt Cancer Center

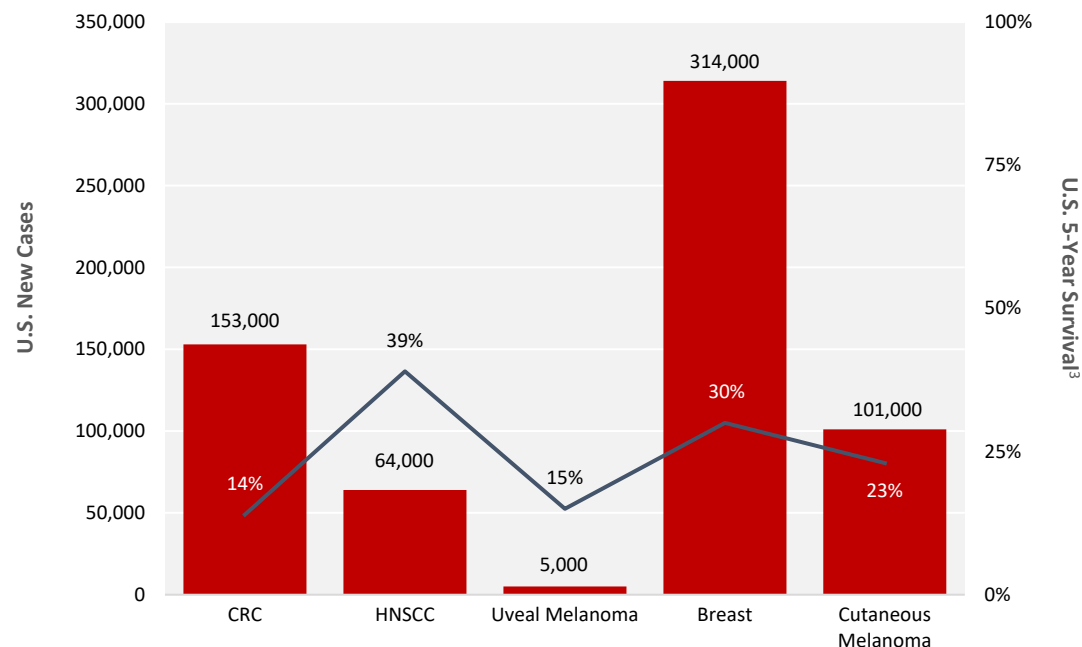
- Colorectal cancer (CRC)
- Head and neck cancer (HNSCC)
- Uveal melanoma
- Cutaneous melanoma

**We intend to provide an initial clinical update across our trials in mid-2024**



# TIDAL-01 Phase 1 Indication Focus on Multiple Solid Tumors with Critical Unmet Need

## New Cases and 5-yr Survival at Metastatic Diagnosis



- With approximately **637K new cases**<sup>1</sup> and **119K deaths**<sup>2</sup> in the U.S. annually, Turnstone is targeting indications with serious disease burdens
- Multiple high-value targets allow for exploration with FIH therapy (some of which are supported by prior academic studies with selected TILs)
- Selected TIL therapies enriched for tumor-reactive T cells have the potential to drive efficacy in both low and high TMB solid tumors

Turnstone intends to demonstrate the benefit of TIDAL-01 in solid tumors where objective response and/or durability of bulk TILs has not been established

<sup>1</sup>American Cancer Society. *Cancer Facts & Figures 2024*; National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER), accessed March 2024; *Melanoma Research Alliance*; Siegel RL, Miller KD, Fuchs HE, Jemal A. *Cancer Statistics, 2021*. *CA Cancer J Clin*. 2021;71(7-33); <sup>2</sup>American Cancer Society. *Cancer Facts & Figures 2024*; Barsouk A, Aluru JS, Rawla P, Saginala K, Barsouk A. Epidemiology, Risk Factors, and Prevention of Head and Neck Squamous Cell Carcinoma. *Med Sci (Basel)*. 2023 Jun 13;11(2):42. doi: 10.3390/medsci11020042. PMID: 37367741; PMCID: PMC10304137; <sup>3</sup>Wang J, Li S, Liu Y, Zhang C, Li H, Lai B. Metastatic patterns and survival outcomes in patients with stage IV colon cancer: A population-based analysis. *Cancer Med*. 2020 Jan;9(1):361-373. doi: 10.1002/cam4.2673. Epub 2019 Nov 6. PMID: 31693304; PMCID: PMC6943094; Barsouk A, Aluru JS, Rawla P, Saginala K, Barsouk A. Epidemiology, Risk Factors, and Prevention of Head and Neck Squamous Cell Carcinoma. *Med Sci (Basel)*. 2023 Jun 13;11(2):42. doi: 10.3390/medsci11020042. PMID: 37367741; PMCID: PMC10304137; *Cancer.net - Breast Cancer - Metastatic: Statistics*; *Cancer.net - Eye Melanoma: Statistics*

# Indication Spotlight: Colorectal Cancer

## Metastatic CRC patients have few effective treatment options

- 1<sup>st</sup> and 2<sup>nd</sup> line options mainly limited to chemotherapy (FOLFIRI / FOLFOX) +/- combinations with bevacizumab and/or anti-EGFR<sup>1</sup>
- 3<sup>rd</sup> line treatment options are mostly targeted therapies with applicability limited to a small percentage of patients with specific mutations (i.e., BRAF-V600E, HER2)<sup>1</sup>

## Unmet need remains high and market size is significant

- After exhausting chemotherapy in 1<sup>st</sup> and 2<sup>nd</sup> line, there are very limited treatment options for the majority of CRC patients
- No approved immunotherapies for MSS-CRC<sup>2</sup>, which comprise 85% of all CRC cases<sup>3</sup>
- Large patient numbers create significant market opportunity for Turnstone in 2<sup>nd</sup> and 3<sup>rd</sup> line metastatic CRC

**Our Phase 1 study is enrolling across all subtypes of 2<sup>nd</sup> and 3<sup>rd</sup> line CRC**

<sup>1</sup>NCCN Guidelines Version 4.2023; [BRAFTOVI](#) Prescribing Information; [Erbix](#) Prescribing Information; [Daiichi-Sankyo](#) Press Release Aug 2023 (Enhertu BTD); [JCO](#) 40, 119-119(2022) (DESTINY-CRC01); [Ann Surg Oncol](#). 2008 Sep;15(9):2388-94; [Cancer Med](#). 2020 Feb; 9(3): 1044–1057; [Onco Targets Ther](#). 2020 Dec 8;13:12601-12613; [Cureus](#). 2023 Jan; 15(1): e33736. [Clin Adv Hematol Oncol](#). 2018 Nov; 16(11): 735–745; [Front Oncol](#). 2022; 12: 888181; [JCO Precis Oncol](#). 2023 Jan;7:e2200179; [Cancers](#) (Basel). 2023 Feb; 15(4): 1022; [Cancers](#) (Basel). 2023 Apr; 15(8): 2288; [1L Nivo Plus Ipi Shows Benefit in mCRC](#); <sup>2</sup>[Dana Farber Cancer Institute](#); <sup>3</sup>Ding K, Mou P, Wang Z, Liu S, Liu J, Lu H and Yu G (2023) The next bastion to be conquered in immunotherapy: microsatellite stable colorectal cancer. *Front. Immunol.* 14:1298524. doi: 10.3389/fimmu.2023.1298524

# Manufacturing Highlights

## Our Current Focus



### Internal Capabilities

Fully operational TIL therapy process and analytical development at our San Diego facility



### External cGMP Manufacturers for TIDAL-01

Completed successful technology transfers and clinical product manufacturing at US sites supporting Ph 1 studies

## Areas of Future Growth

### ☐ Manufacturing Time:

We are optimizing the overall manufacturing time towards our target of 4 weeks and expect that all steps will be implemented prior to start of pivotal trials

### ☐ In-House Manufacturing:

We are designing and intend to develop a fully integrated commercial manufacturing supply chain once clinical success of TIDAL-01 is demonstrated

**Our primary focus for Phase 1 development is to demonstrate a consistent and reproducible TIDAL-01 product with target dose numbers in our desired indications**



# EMERGING PORTFOLIO AND COMPETITIVE PROFILE



# Emerging Pipeline with Significant Upside Potential

Turnstone is building a TIL pipeline to **further broaden objective responses** and treat patients in earlier lines of therapy

## TIDAL-02

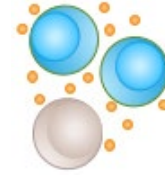
**Selected TILs with next-generation manufacturing and TIL functional and quality enhancements**

### Direct Selection



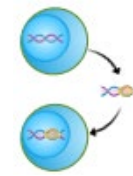
Proprietary combination of selection markers on tumor-reactive T cells to enable physical sort of reactive vs. bystander cells

### Enhanced Isolation and Expansion



Culture media supplements added to improve and maintain TIL quality and function<sup>1</sup>

### Gene Editing

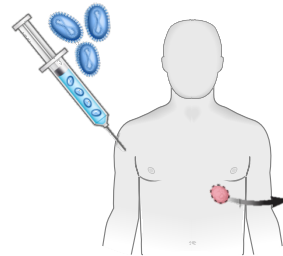


Gene edits designed to minimize dependence on exogenous IL-2 and resist exhaustion post infusion

## Selected TILs + Virus

**Viral immunotherapy pre-treatment and post-treatment in combination with TIDAL-01**

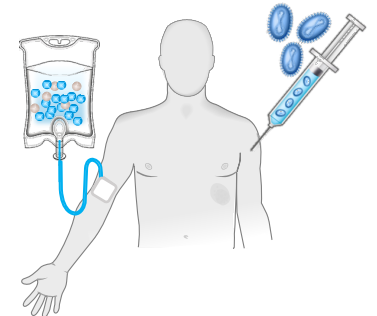
### Pre-treatment: Expand access to indications less amenable to TIL therapy by optimizing TIL extraction



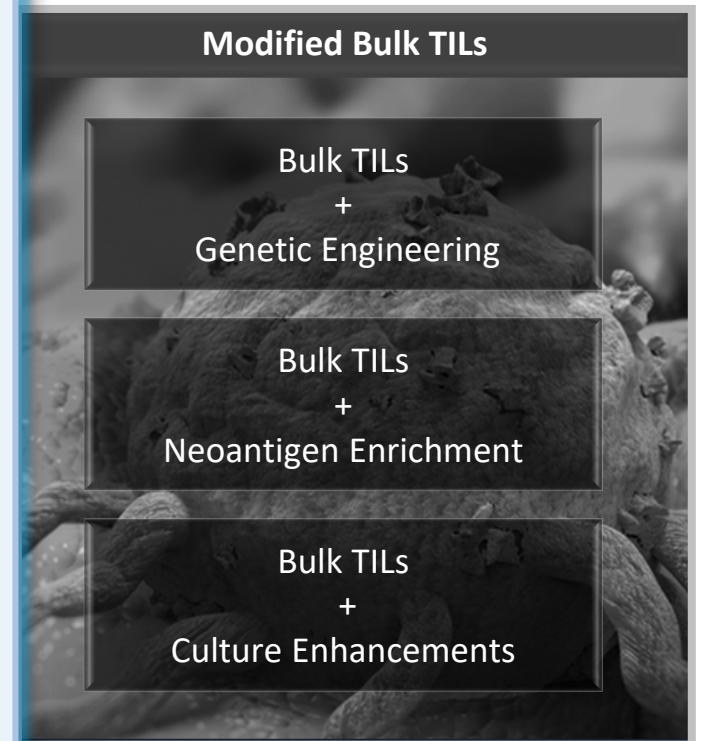
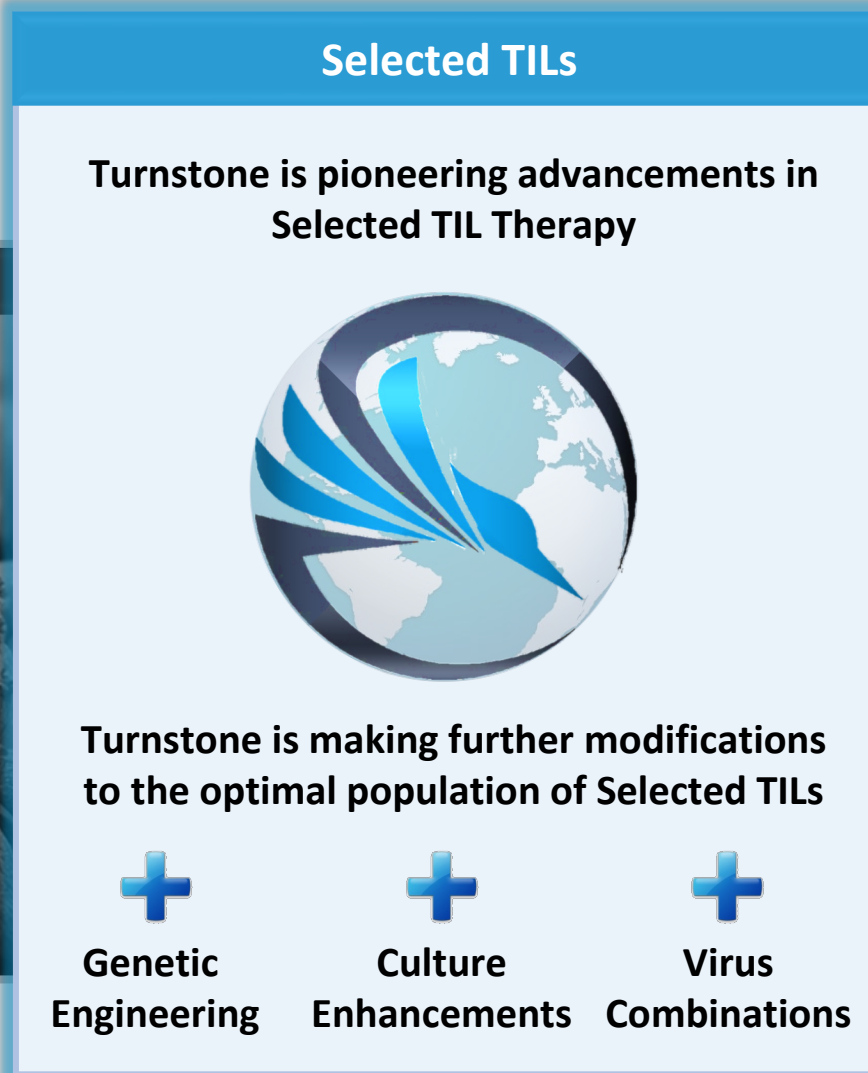
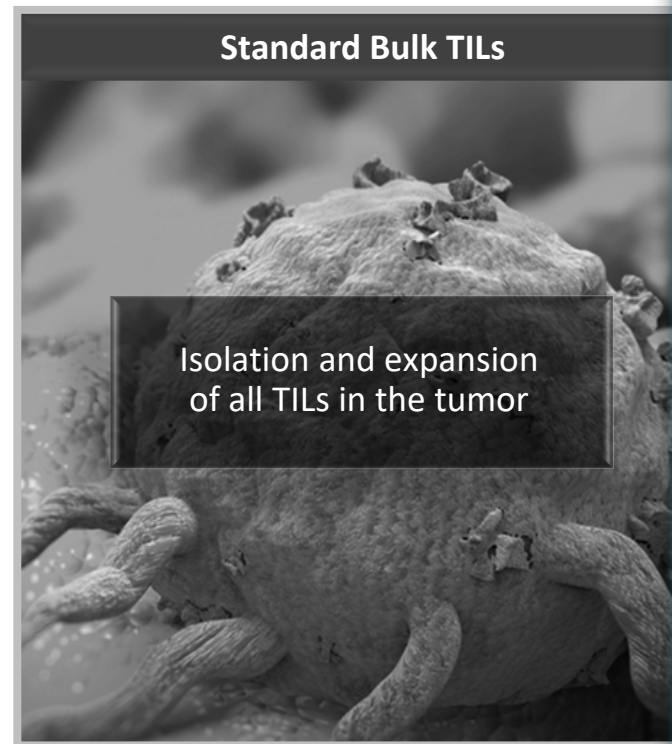
Drive a more diverse population of tumor-reactive T cells and increase T cell trafficking to tumor for superior quality and quantity of TIL harvest

### Post-treatment: Reprogram tumor with viral immunotherapy to improve the objective response of TIL treatment

Reprogram the immunosuppressive tumor microenvironment (e.g., turn a “cold” tumor “hot”) potentiating TIL infiltration, function, and proliferation within the tumor



# Turnstone Competitive Positioning



# Turnstone Biologics Highlights



**TILs have been recently approved by the FDA** for the treatment of cutaneous melanoma



Academic studies provide early **clinical evidence for next-generation selected TIL** approach in multiple solid tumors



Turnstone is developing Selected TILs to **broaden potential treatment across the majority of solid tumors**



We are currently evaluating TIDAL-01 in multiple Phase 1 clinical trials focused on **CRC, HNSCC, uveal melanoma, breast cancer and cutaneous melanoma**



**Initial clinical update from Phase 1 TIDAL-01 studies anticipated in mid-2024**

**Thank You**