
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 8, 2019**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

001-35994

(Commission File Number)

26-2844103

(IRS Employer Identification No.)

**801 Capitola Drive
Durham, NC 27713**

(Address of principal executive offices and zip code)

(919) 240-7133

(Registrant's telephone number including area code)

N/A

(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of 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))

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 checkmark 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 8.01. Other Events.

Heat Biologics, Inc. (the “Company”) will be making corporate presentations over the next several weeks. In connection with the presentations, the Company intends to discuss the slide presentation attached as Exhibit 99.1 hereto, which is incorporated herein by reference.

The slide presentation attached as Exhibit 99.1 to this Current Report on Form 8-K includes “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the slide presentation or in the press release are “forward-looking” rather than historical.

The Company undertakes no duty or obligation to update or revise information included in this Current Report on Form 8-K or Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Heat Biologics, Inc. investor presentation dated January 2019



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: January 8, 2019

HEAT BIOLOGICS, INC.

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chairman, President and
Chief Executive Officer



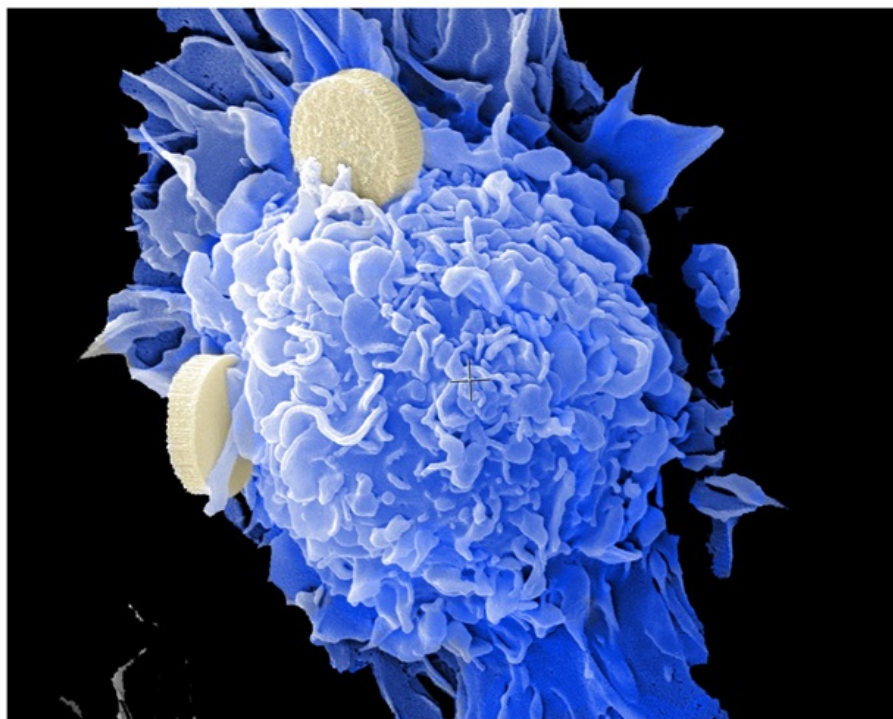
EXHIBIT INDEX

Exhibit Number	Description
99.1	<u>Heat Biologics, Inc. investor presentation dated January 2019</u>



Heat Biologics

Corporate Presentation
January 2019



Forward Looking Statements

This presentation includes statements that are, or may be deemed, “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. 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” or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drugs targeting cancer, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to complete clinical trials and make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our ability to partner our product development, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, the industry in which we operate and the trends that may affect the industry or us.

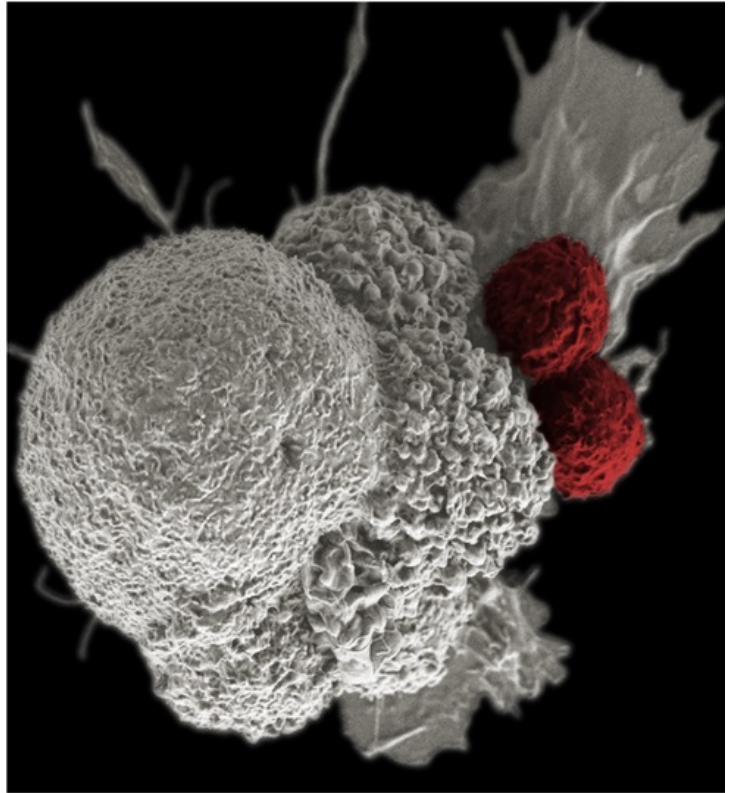
By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation as a result of, among other factors, the factors referenced in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2017 and our quarterly report on Form 10-Q for the subsequent quarters (collectively, our “SEC Filings”). In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation, except as required by law.

You should read carefully the factors described in the “Risk Factors” sections of our SEC Filings to better understand the risks and uncertainties inherent in our business.

Our Mission

To activate CD8+ “Killer” T-cells to turn “**COLD**” tumors “**HOT**”

We seek to combine with checkpoint inhibitors and other immunotherapies to dramatically increase their effectiveness



Investment Highlights

Potential Best in Class Oncology Treatment - T-cell activating platform (TCAP) produces allogeneic, off-the-shelf therapies designed to activate the immune system to turn immunologically “cold” tumors “hot”

Combination Effect - Our therapies are designed to be administered with checkpoint inhibitors and other immuno-modulators to enhance immune response

Off-the-shelf Therapies - We can administer drug immediately without extracting patient material, simplifying treatment and substantially lowering cost of goods sold

Clinical Data with Checkpoint Inhibitors - Positive interim data from ongoing Phase 2 trial of HS-110 + checkpoint inhibitor in non-small cell lung cancer (NSCLC)

Diverse Technology Platforms - Multiple complementary platform technologies

Strong Management Team - Senior team with broad experience in biotech, pharma, clinical development and research



- Tumors that **have not been** subject to robust CD8+ “Killer” T-cell attack
- Biopsied tumors contain minimal CD8+ T-cells



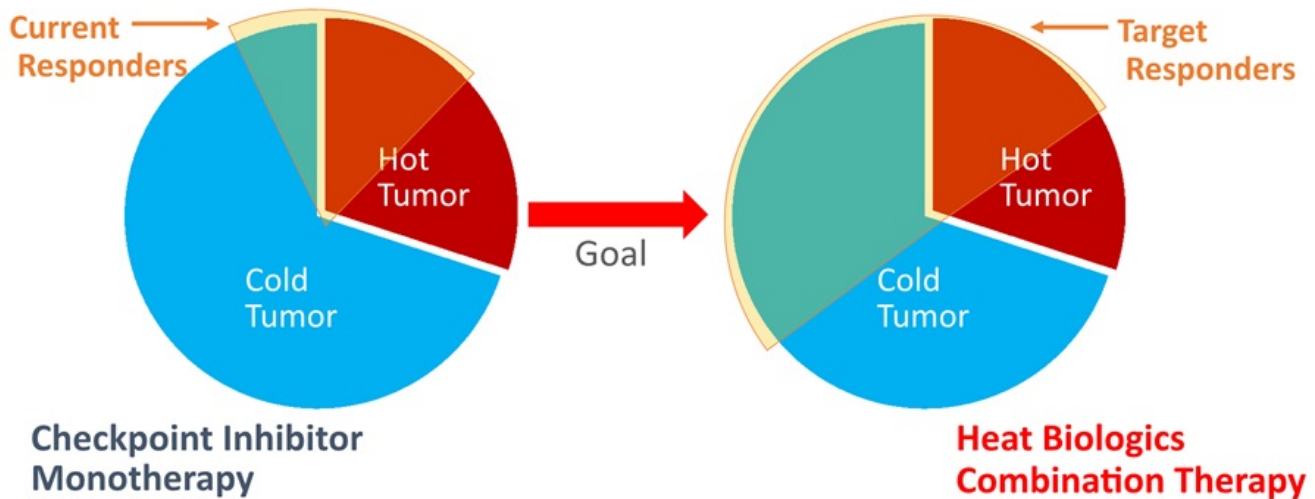
- Tumors that **have been** subject to robust CD8+ “Killer” T-cell attack
- Biopsied tumors are loaded with CD8+ T-cells

HOT tumors are associated with clinical response

Current NSCLC checkpoint inhibitor treatment

Unmet medical need in 2nd line NSCLC

17% - 20% response rate in a PD-L1 unselected population*



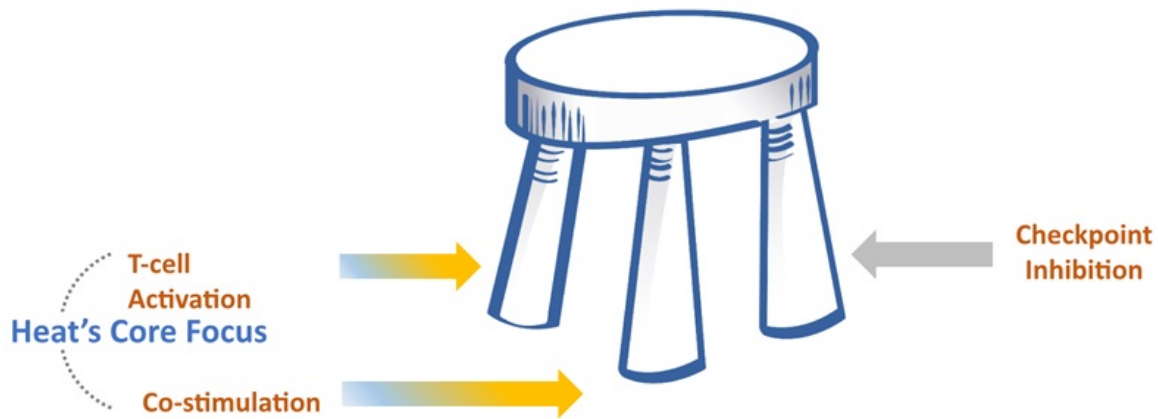
Combination therapies can improve patient outcomes

*Borghaei H, et al. NEJM 2015;373:1627-39

*Nishio M, et al. JCO 2015; 33:15_suppl, 8027-8027

Immuno-Oncology Combination Therapy

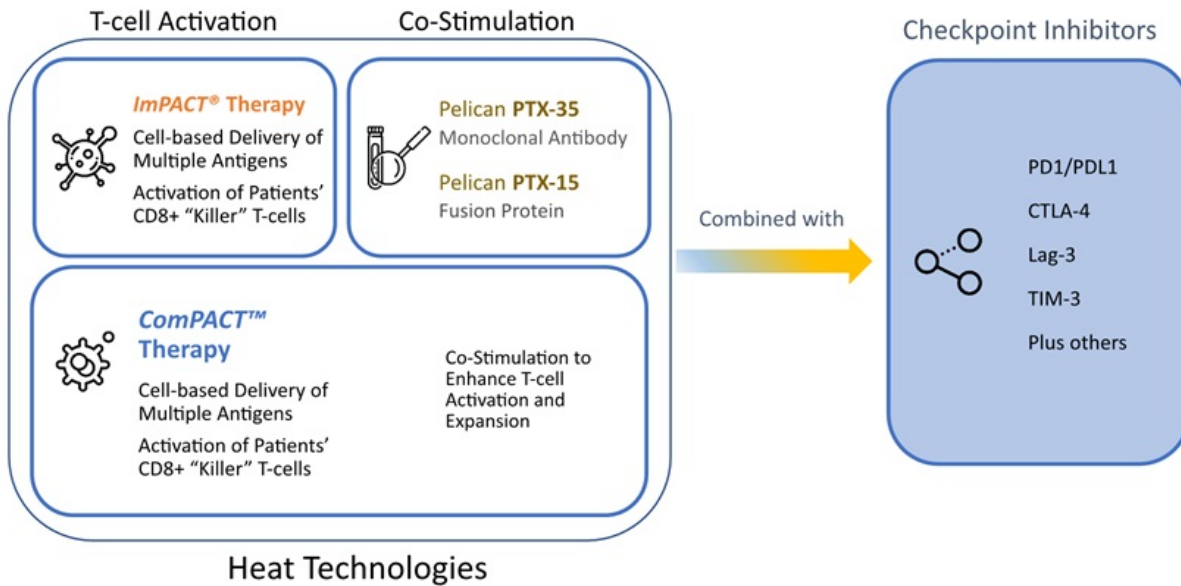
The three legs of an Immuno-Oncology Stool



Heat's goal is to **dramatically increase** the number of patients responding to checkpoint inhibitors

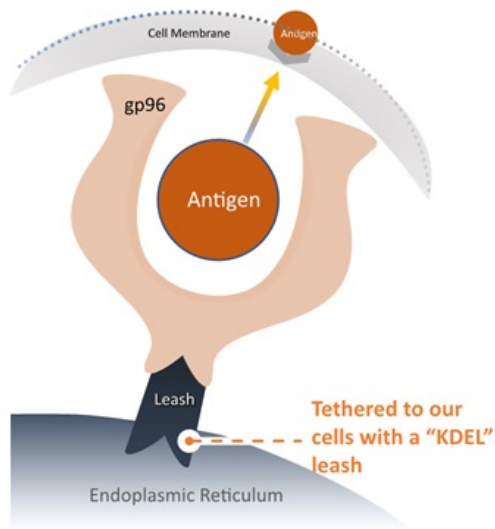
Combination Therapies

Unlocking the Body's Natural Defenses with a Broad Range of Combination Therapies



Introducing gp96

*The Immune System's "Swiss Army Knife"**



"Molecular Warning System"

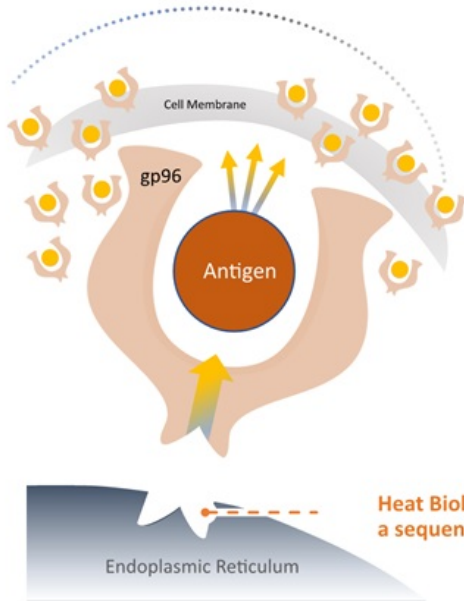
- Natural biological process to deliver proteins (antigens) & gp96 adjuvant to our immune system
- Gp96 "chaperones" newly-created proteins to the cell membrane where they are released and embedded
- Activates a cytotoxic T-cell response to the antigen it is carrying when cells die through necrosis
 - Enables MHC I antigen cross-presentation to CD8+ T-cells
- Gp96 + protein are only naturally released via necrosis
 - Exposure of gp96 outside the cell activates an immune response to the antigen it is carrying
 - Enables MHC I antigen cross-presentation specifically to CD8+ T-cells
- Among the most powerful adjuvants and the only adjuvant to show exclusive specificity to CD8+ ("killer") T-cells
 - Provides long-term immunity against the infectious agent

*Schild, H. & Rammensee, H. *Gp-96 – The Immune System's Swiss Army Knife*. *Nature Immunology* 2, 100-101 (2000)

ImPACT Platform

"Severing the Leash"

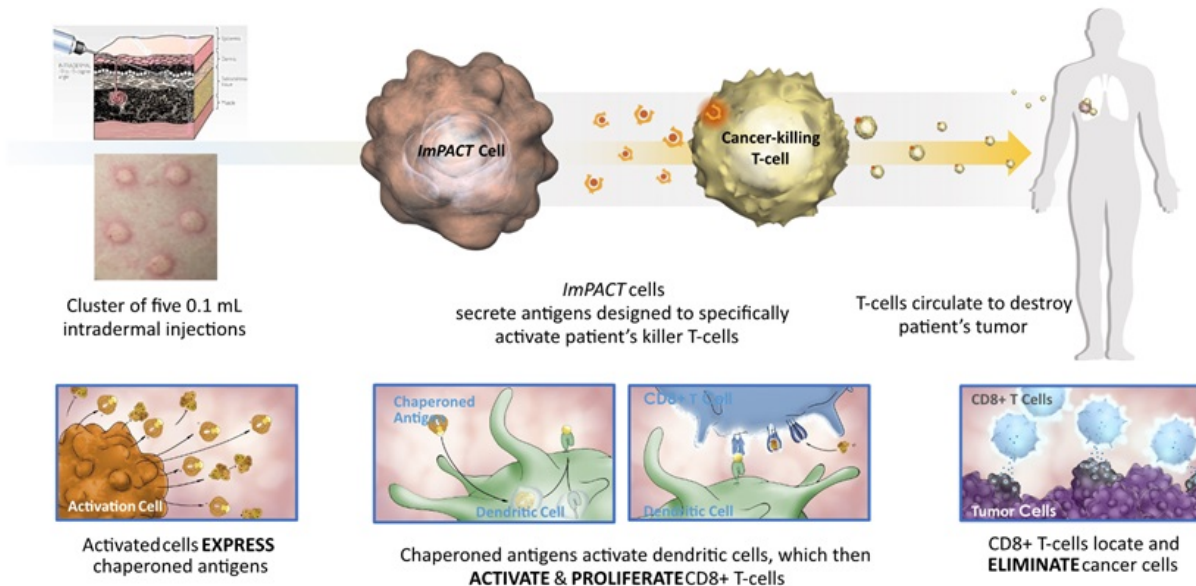
Heat Biologics/ImPACT® technology reprograms cancer cells to continuously secrete their own antigens bound to heat shock protein gp96 to seek out and destroy a variety of tumors



- Genetically modify tumor cells by “severing the leash” that binds the gp96 to the endoplasmic reticulum of the cell and replacing it with a sequence that pumps gp96 out of the cell
- Enables living cancer cells to “pump-out” their own surface antigens along with their gp96 chaperone
 - Mimics necrotic cell death
- Activates a powerful pan-antigen cytotoxic T-cell immune response

Heat Biologics ImPACT technology removes the leash that binds gp96 to the cell, replacing with a sequence that allows cells to continually secrete gp96 along with their “chaperoned” antigen

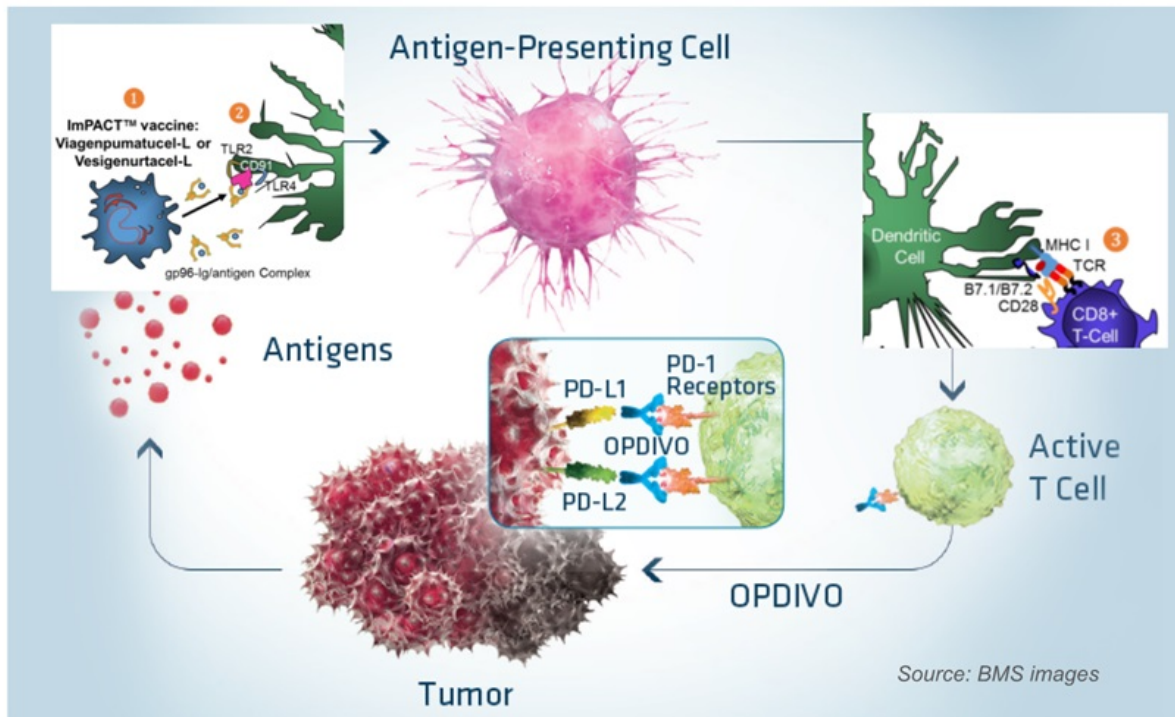
ImPACT®: Immune Pan-antigen Cytotoxic Therapy



Heat's unique cell-secreted gp96 drives activation of dendritic cells via TLR signaling and CD8+ T cells via antigen cross presentation

ImPACT + Opdivo Combination Therapy

Potential to improve clinical responses and survival, without additional toxicity



Product Pipeline

Combination Therapies Designed to Activate CD8+ T-cells Against Cancer

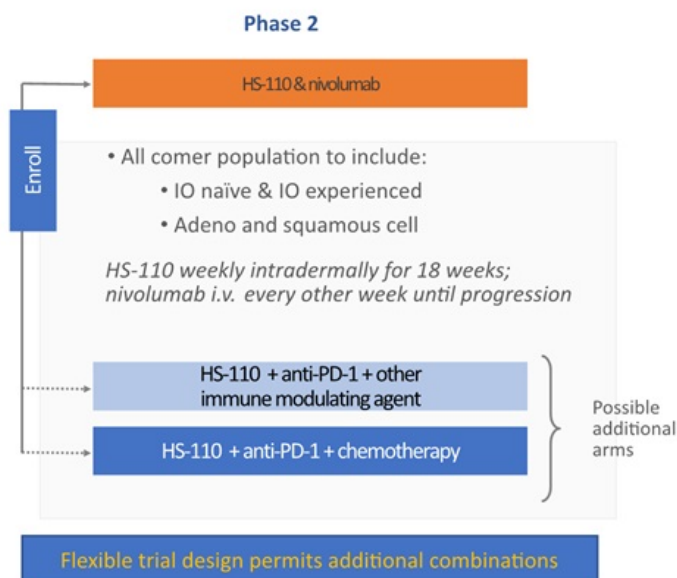
Combination Therapies	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	Approved	Comments
HS-110 (viagenpumatucl-L)	NSCLC	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	ImPACT® activation technology in combination with nivolumab and other checkpoint inhibitors TBA
HS-130	NSCLC	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	ComPACT™ activation technology in combination with checkpoint inhibitors TBA
Co-stimulators							
PTX-35	TBA	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	Humanized monoclonal antibody, functional agonist of human TNFRSF25 (\$15.2MCPRIIT grant)
PTX-15	TBA	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	TL1A-Ig fusion protein, functional agonist of human TNFRSF25

- Clinical proof of mechanism activating an immune response
- Activated T-cell immune response seen at 10 weeks
- T-cell infiltration seen deep inside tumors
- Positive safety profile to date

HS-110 (DURGA) Phase 2 Master Protocol: Design

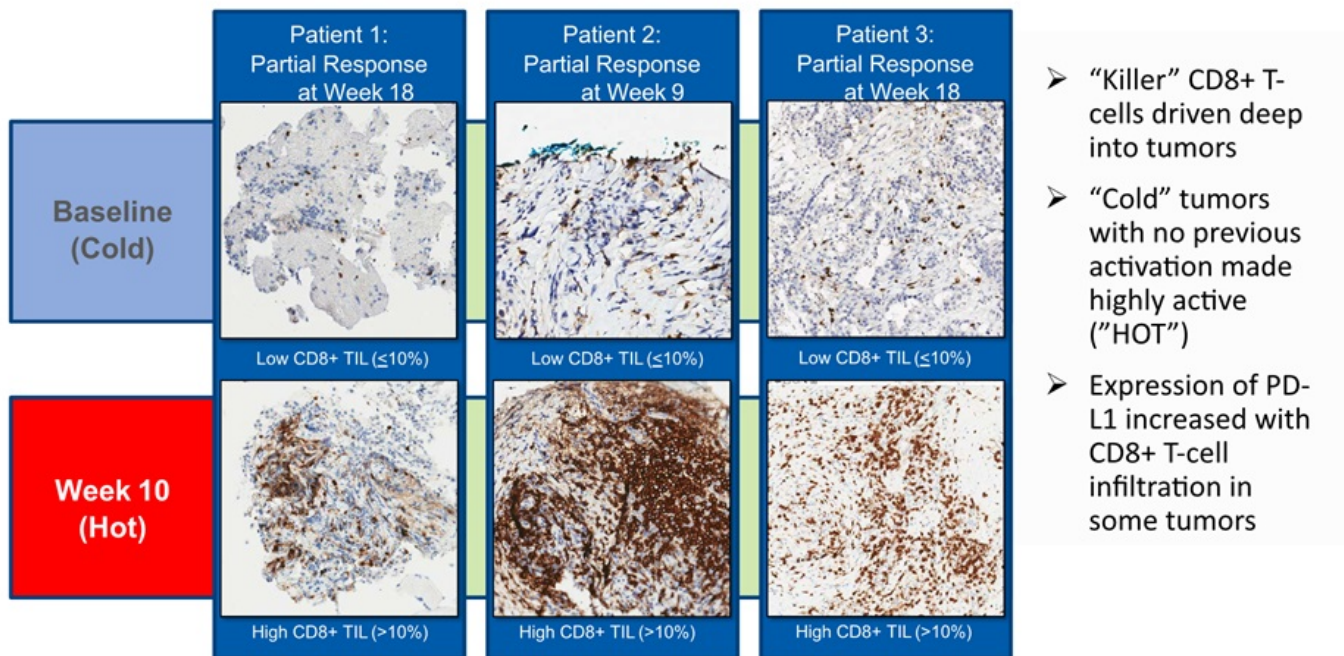
A Phase 1b/2 study of Viagenpumatulcel-L (HS-110) in Combination with Multiple Treatment Regimens in Patients with Non-Small Cell Lung Cancer (the "DURGA" Trial)

Objective	<ul style="list-style-type: none"> Evaluate objective response rate of HS-110 and anti-PD-1 immune checkpoint inhibitor and other agents
Patient Population	<ul style="list-style-type: none"> NSCLC Adenocarcinoma and squamous cell carcinoma 2nd line therapy
Endpoints	<ul style="list-style-type: none"> Safety and tolerability, immune response, objective response rate, duration of response, overall survival and progression-free survival
Enrollment	<ul style="list-style-type: none"> Up to 25 U.S. sites Up to 120 patients TBD by iDMC Partnership with Yale Cancer Center on TIL analysis



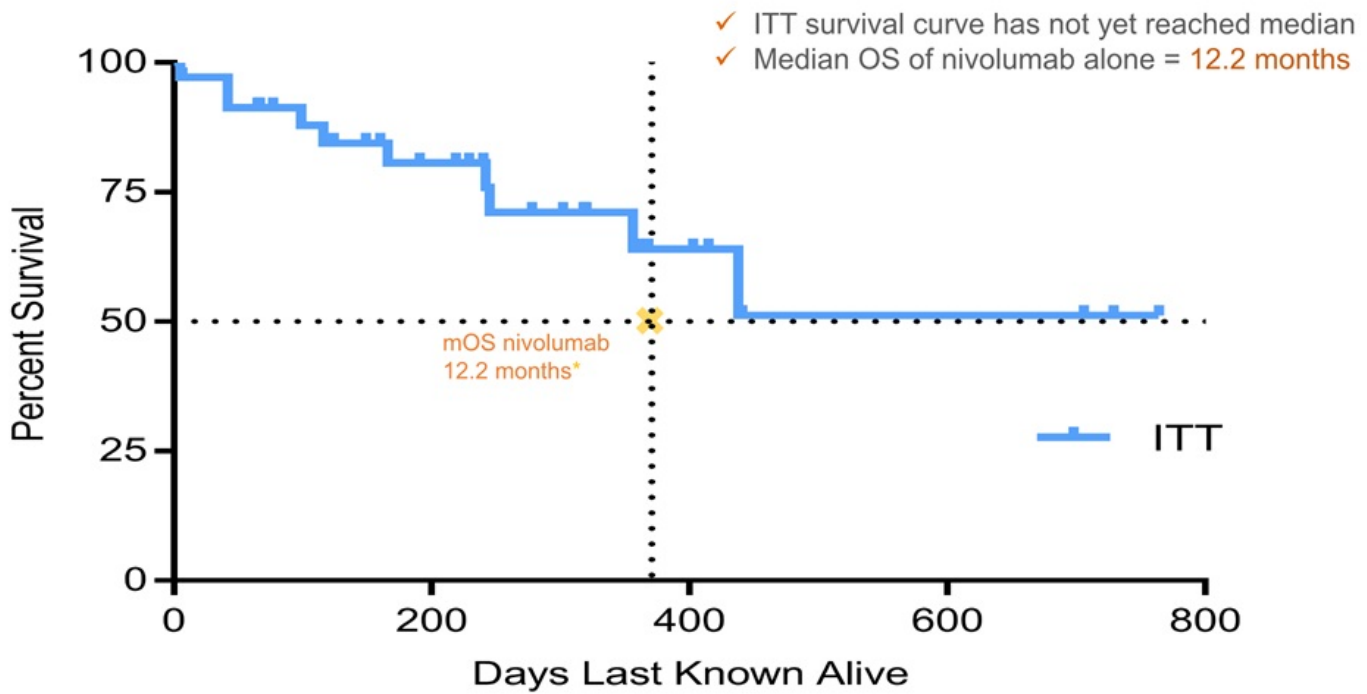
Early Results from DURGA Trial:

Clinical Evidence that HS-110 is Turning COLD Tumors HOT

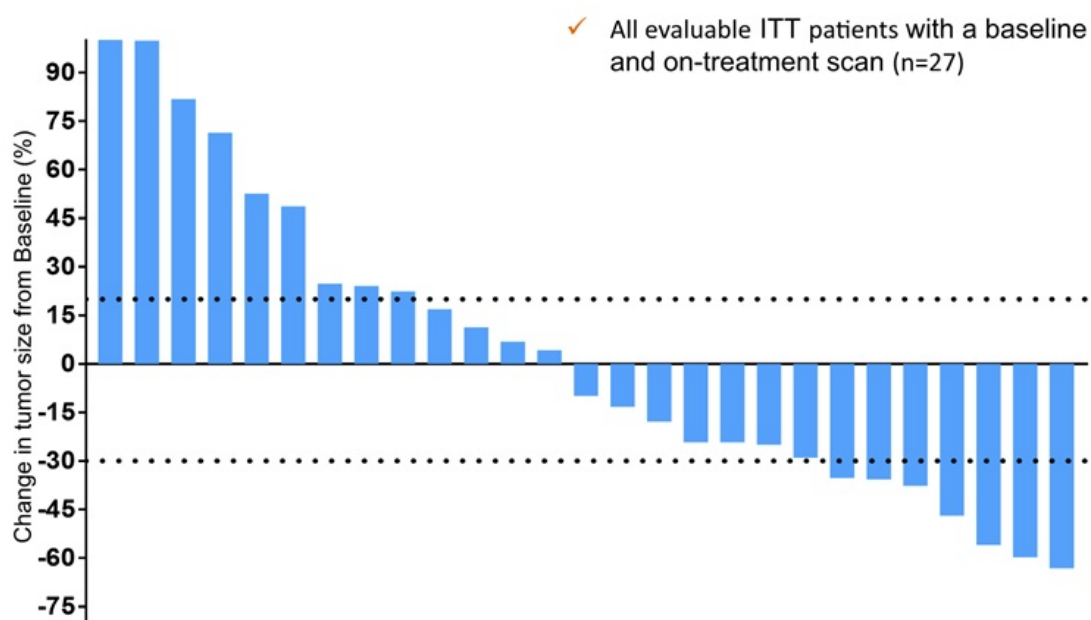


TIL Infiltration Associated with Clinical Response

Survival Data Are Still Maturing Median Overall Survival Not Yet Reached

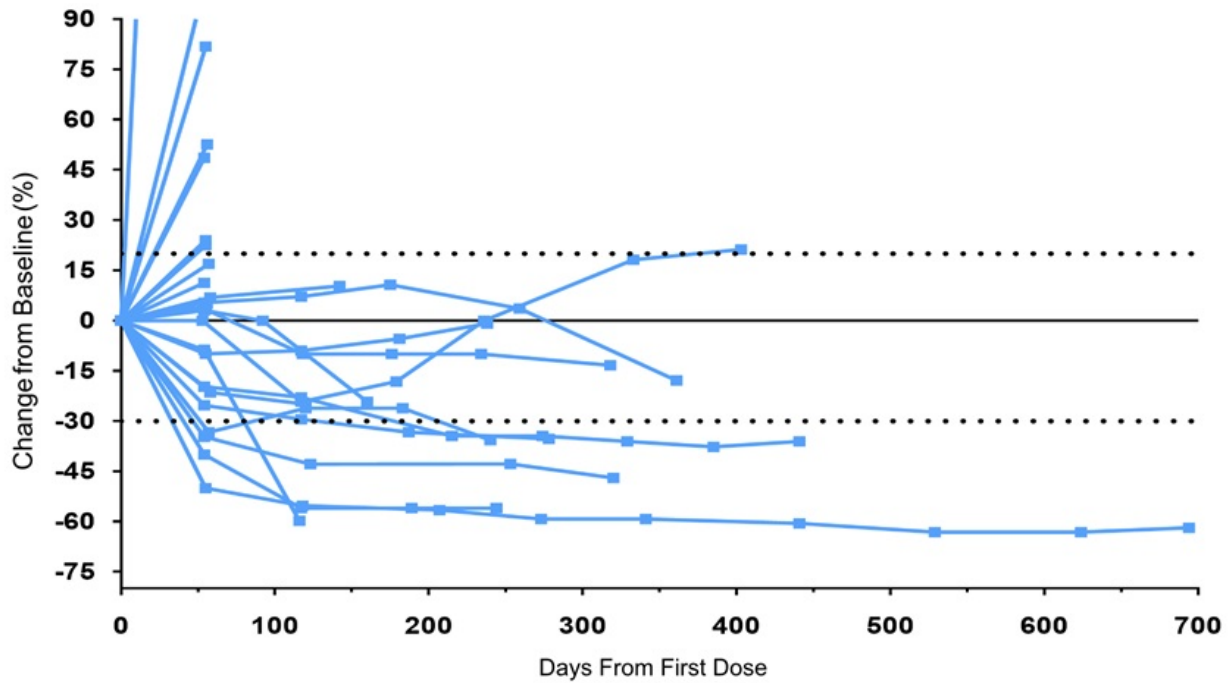


Best Target Lesion Response



All enrolled patients (ITT) with a baseline and on-treatment scan

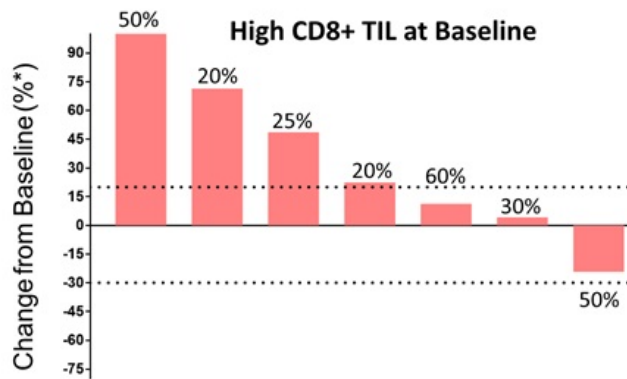
Overall Target Lesion Responses are Durable and Long Lasting



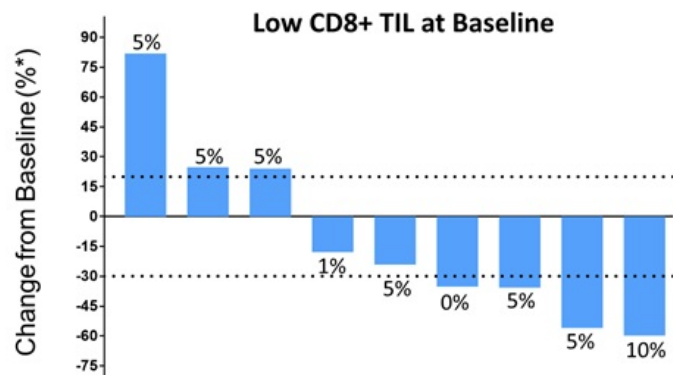
All enrolled patients (ITT) with a baseline and on-treatment scan

Encouraging data in “Cold Tumor” Patients Who Typically Do Not Respond Well to PD-1 Inhibitors

Target Lesion Response Based on Initial CD8+ TIL Status



>10% CD8+ TIL at Baseline



≤10% CD8+ TIL at Baseline

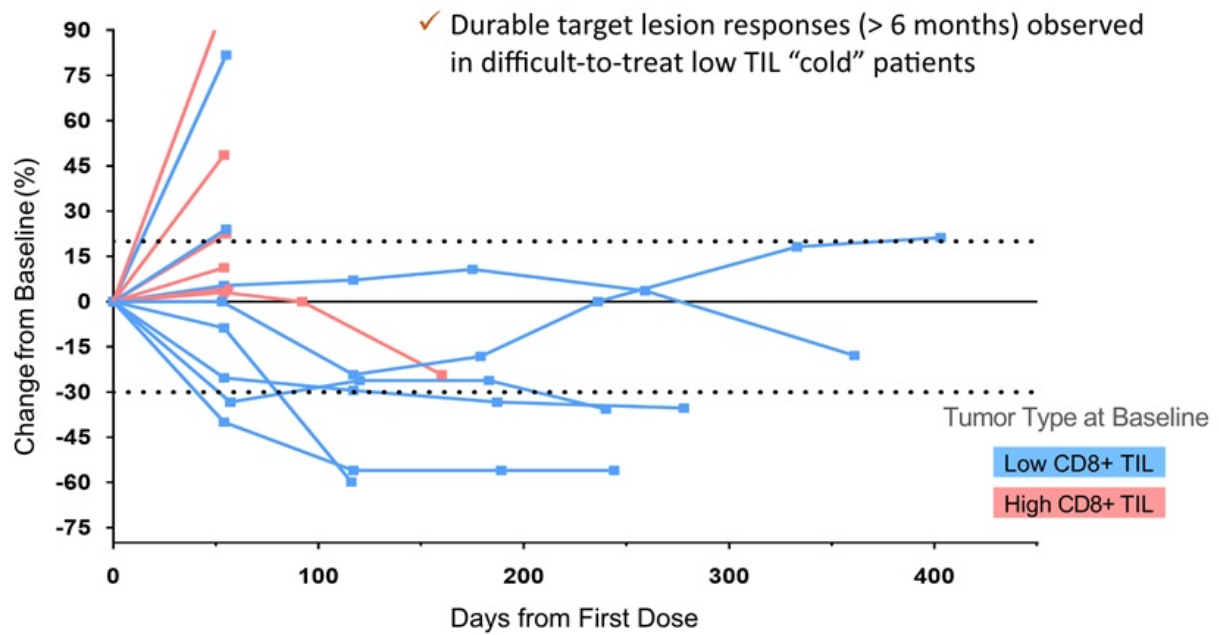
4 of 9 low CD8+ TIL achieved a partial clinical response

* % of CD8+ T-cells in tumor tissue at baseline

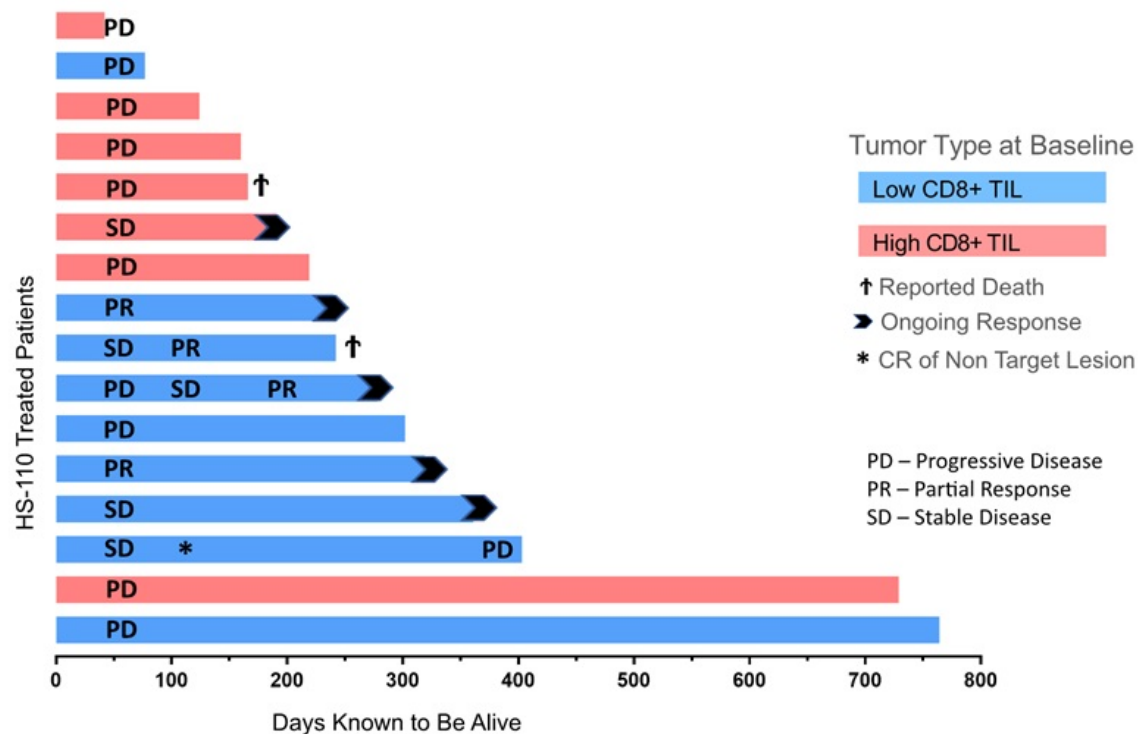
CD8+ TIL Evaluable ITT Population

19

Durable Target Lesion Responses Based on Initial CD8+ TIL Status

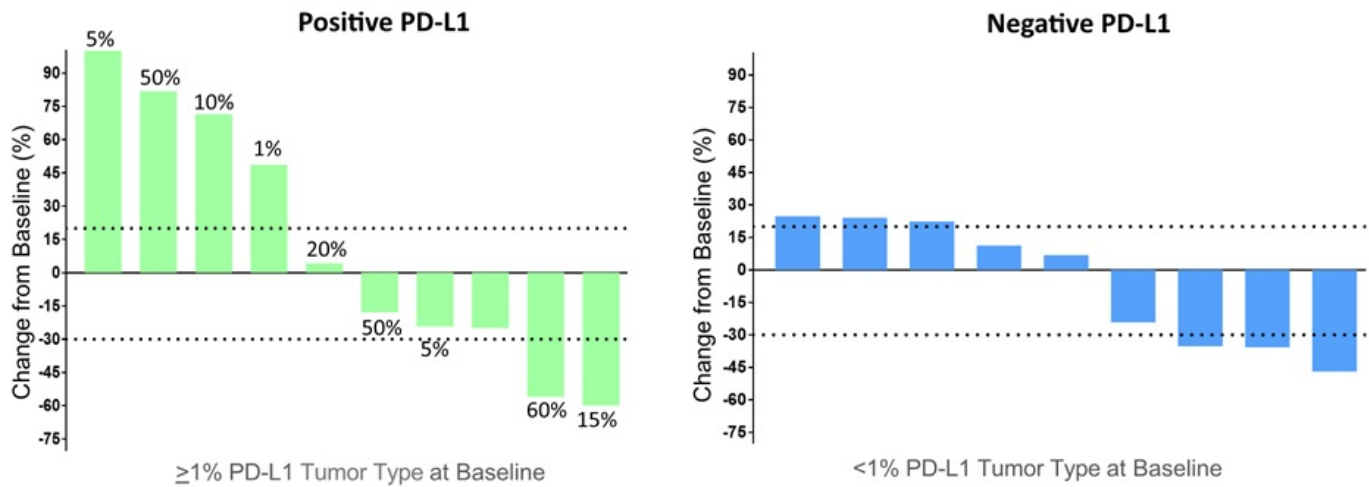


Encouraging Overall Survival Based on CD8+ TIL Status



TIL Evaluable ITT Population

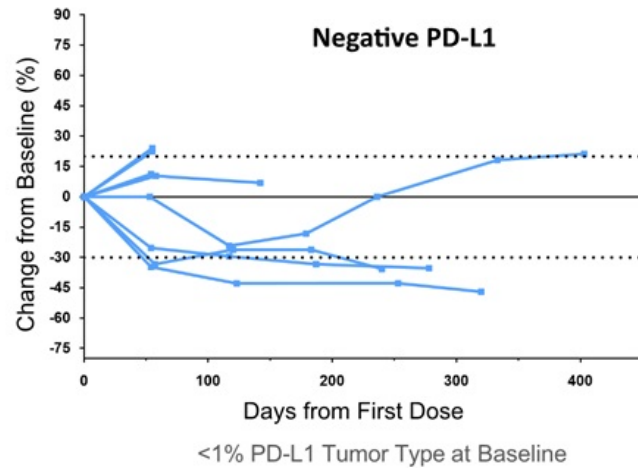
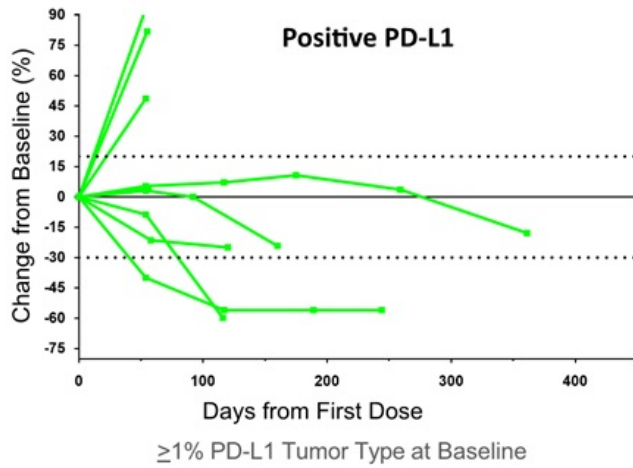
Encouraging Data in Low PD-L1 Patients Who Typically Do Not Respond to Checkpoint Inhibitors



Target Lesion Response Based on Initial PD-L1 Status

PD-L1 Evaluable ITT Population

Durable Target Lesion Responses Observed in Difficult-to-Treat Low PD-L1 Patients



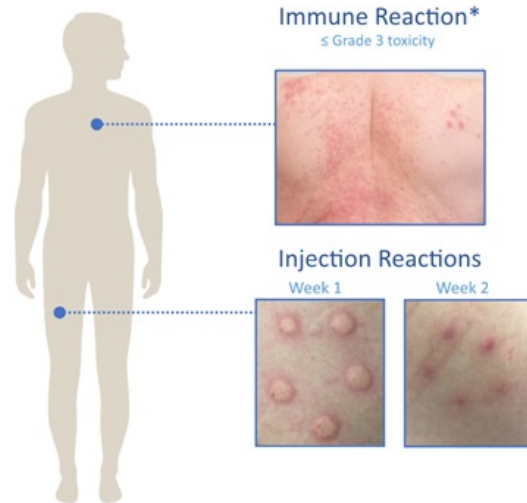
Durable Target Lesion Responses Based on Initial PD-L1 Status

PD-L1 Evaluable ITT Population

HS-110 Shows Favorable Safety Profile to Date

~1,000 HS-110 Doses – No Serious Adverse Reactions

- Only one patient ended treatment due to a non-serious adverse reaction*
- No systemic use of steroids required to treat reactions
- No serious adverse reactions beyond those seen with standard of care
- No additive toxicities to standard of care



**Represents the only patient of ~100 patients dosed with HS-110 who discontinued treatment for a study related adverse event*

Summary of Phase 2 Interim Data

- Tumor shrinkage and disease control demonstrated in a majority of evaluable patients
 - Overall responses are durable and long lasting
 - Median overall survival has not yet been reached
- HS-110 shows effect in difficult-to-treat low TIL and low PD-L1 patients who typically do not respond to checkpoint inhibitors
 - HS-110 shows durable responses in low TIL “cold tumor” patients
 - HS-110 shows durable responses in low PD-L1 patients
- A trend of survival benefit is observed with higher ELISPOT activity reflective of tumor antigen-specific immune response

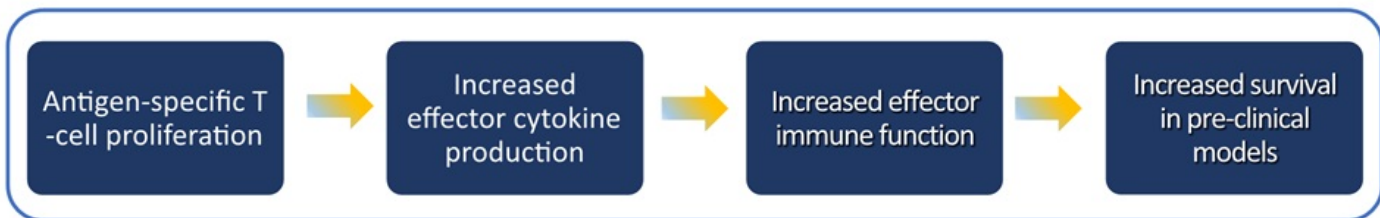
Heat Biologics Acquires Pelican Therapeutics



Unlocking the Body's Natural Defenses with a Broad Range of Combination Therapies

- Heat **acquired 80% controlling interest** in Pelican in May 2017
- Pre-clinical synergy with Heat's *ImPACT*® and checkpoint therapy
- **\$15.2M grant award** from the Cancer Prevention Research Institute of Texas (CPRIT) propels PTX-35 through a **~70-patient, first-in-human clinical program**
- PTX-35 is a potential **best-in-class, T-cell co-stimulator** specific to "killer" CD8+ "memory" T-cells

Pre-clinical studies highlight advantages over competing T-cell co-stimulator programs based on CD8+ T-cell specificity



Only Pelican is targeting TNFRSF25, an emerging target in immuno-oncology

Highlights from Pelican Pre-clinical Studies

- TNFRSF25 is preferentially expressed on CD8+ T-cells compared to other T-cell co-stimulators
 - Co-stimulation occurs only in the context of **TCR recognition of antigen**
 - Drives the development of **antigen-specific CD8+ T-cells** (mimics TL1A, the specific ligand of TNFRSF25)
 - Superior activity is seen with TNFRSF25 in stimulating memory CD8+ cells relative to OX40, 4-1BB and GITR
 - Agonism with TNFRSF25 mAb increases:
 - Effector cytokine function
 - Effector immune function
 - Survival in mouse models
 - TNFRSF25 mAb results in increased survival compared to agonism of OX40, GITR, 4-1BB with respective agonist mAbs in mouse melanoma models
-

Corporate Milestones



Corporate Highlights

Nasdaq HTBX	Shares Outstanding 32.5M	Share Price \$1.06¹	Market Cap \$34.4M¹	Cash & Equiv. \$27.7M^{2,3}	Grant Funds \$15.2M
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Capitalization table (as of 12.31.2018)	Shares	WAEP	% of Fully Diluted
Common shares outstanding	32,494,019		70.3%
Warrants	9,030,730	\$1.89	19.5%
Outstanding stock options	3,081,124		6.7%
Unvested restricted stock	1,635,698		3.5%
Fully Diluted Shares Outstanding	46,241,571		100%

1. Closing price as January 2, 2018

2. Includes November 2018 financing

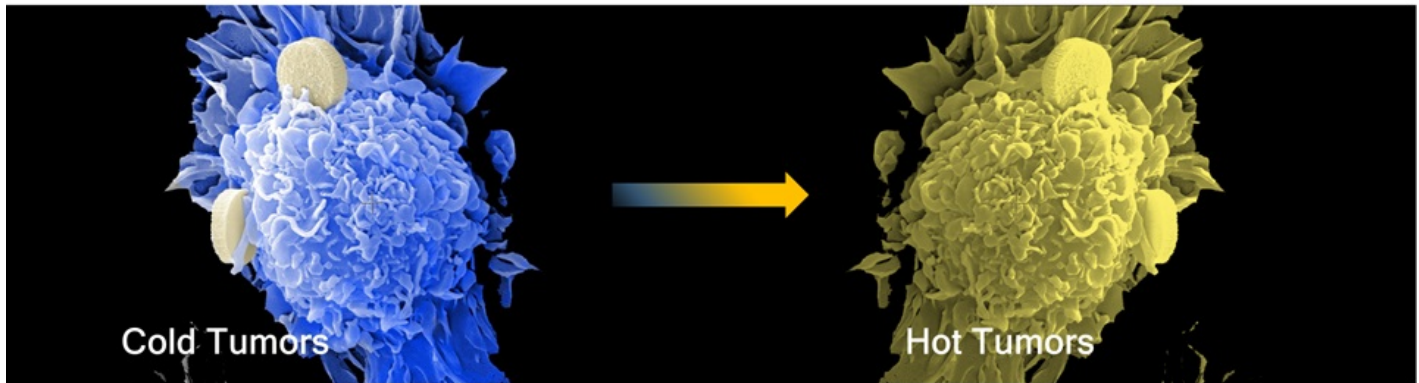
3. Does not include grant funding due to Heat or its subsidiaries

Investment Highlights

- Potential Best in Class Oncology Treatment
- Off-the-shelf Therapies
- Clinical Data with Checkpoint Inhibitors
- Diverse Technology Platforms
- Strong Balance Sheet



Turning **COLD** Tumors **HOT**



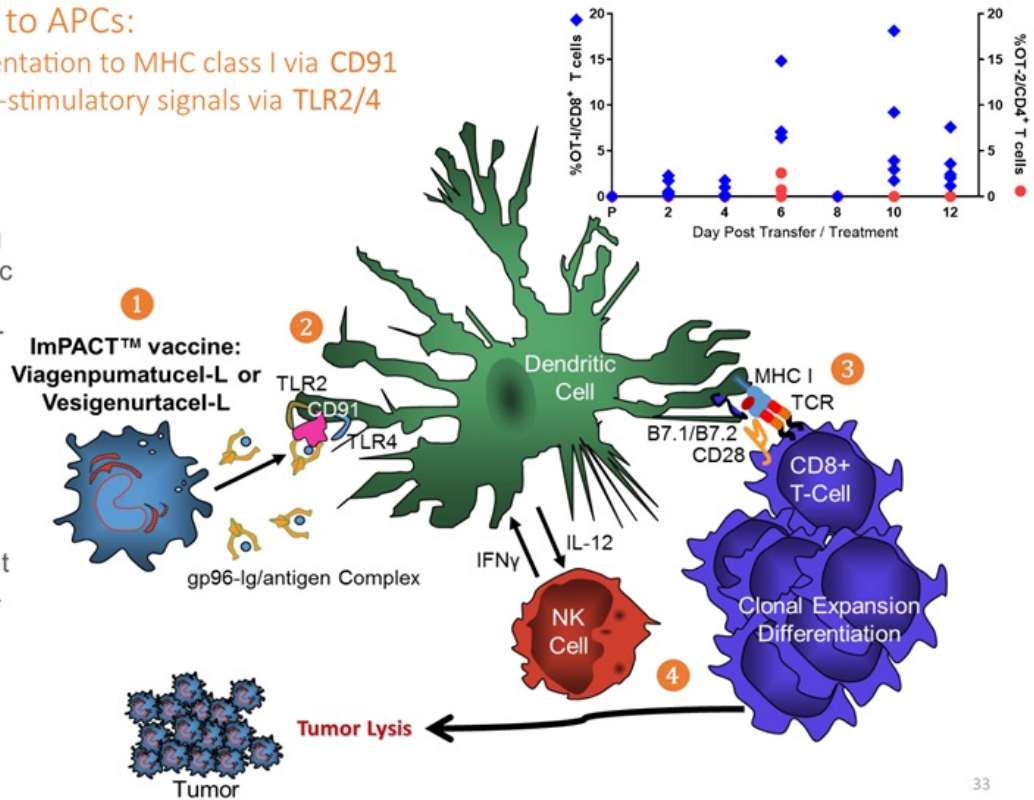
Appendix

ImPact Generates an Adaptive Immune Response

2 signals Delivered to APCs:

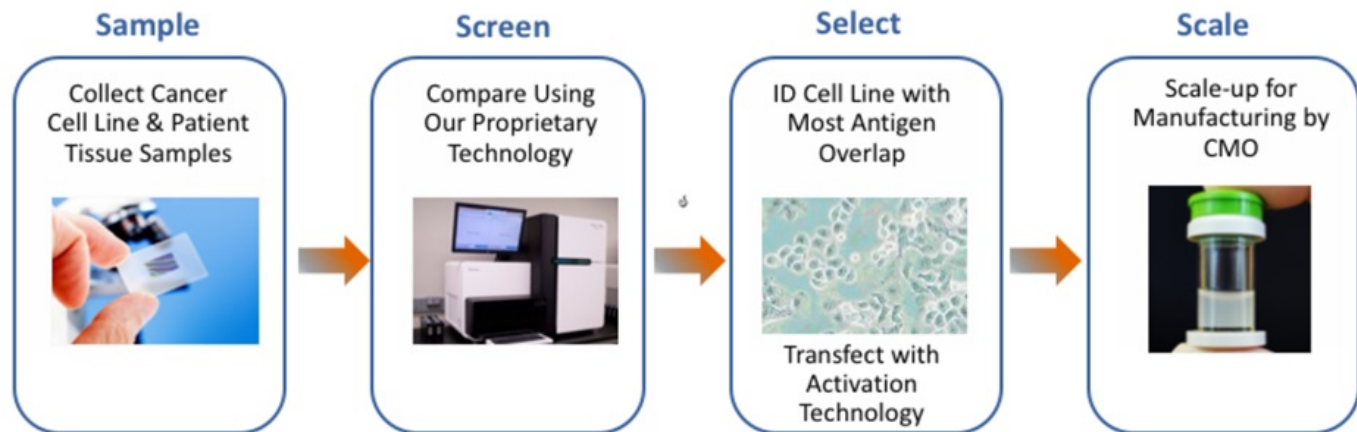
- ✓ Antigen cross presentation to MHC class I via CD91
- ✓ Up regulation of co-stimulatory signals via TLR2/4

1. **Secretion of gp96-Ig**
carrying tumor specific proteins represented on the patients tumor
2. **Activation of APCs**
(TLR2/4) and cross-presentation of antigens (CD91)
3. **Specific T-cell receptor**
engagement
4. **Clonal Expansion** of
Tumor Antigen Specific T cells.



ImPACT[®] Manufacturing

Robust, Multi-antigen T-cell Activation



- Frozen, fully-diluted single-dose vial
- Final drug product: 1 million or 10 million cells
- Easily scaled manufacturing

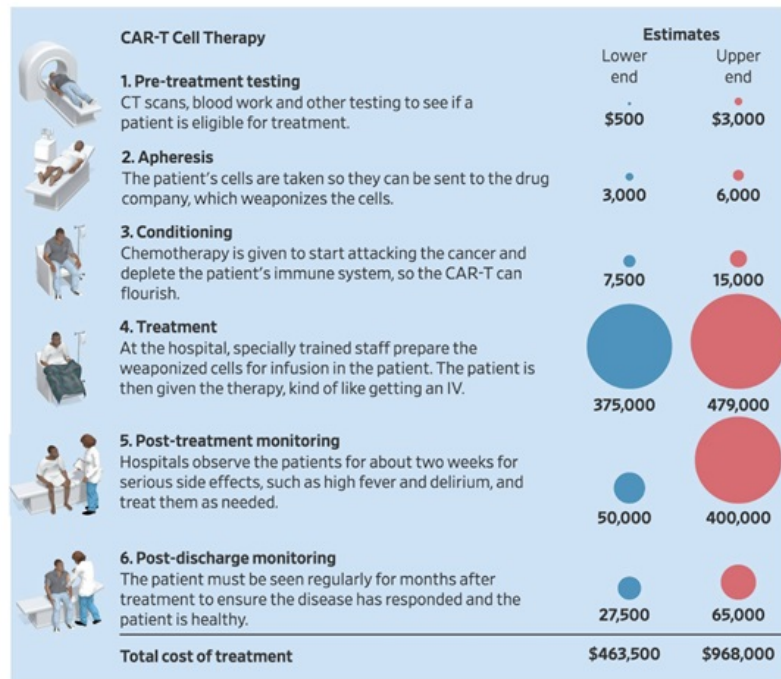
Low COG, off-the-shelf alternative to autologous therapies

Cost-Effective Therapy

Them – Autologous Approach

Million-Dollar Treatment

A new wave of gene-based therapies for cancer and other diseases threatens to bring the cost of treatment to a million dollars, because both the drug and related care are expensive.



Source: "The Million-Dollar Cancer Treatment: Who Will Pay?", WSJ, 4/28/18

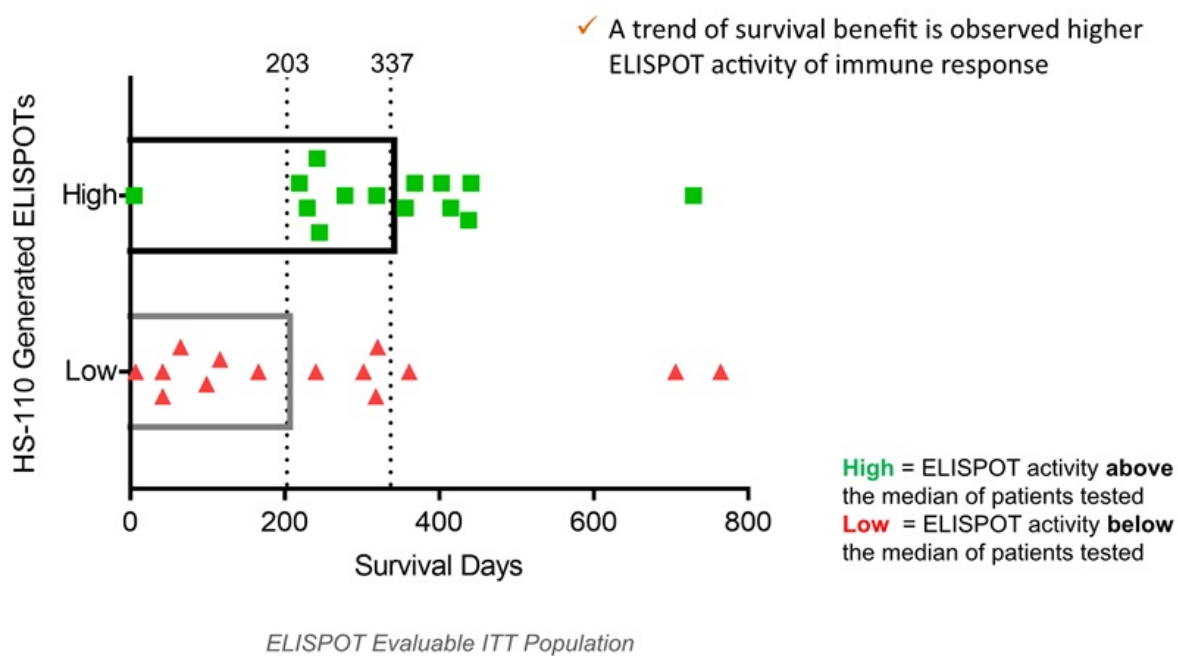
Us – Allogeneic Approach

Scalable, low cost manufacturing and delivery relative to autologous cell therapies



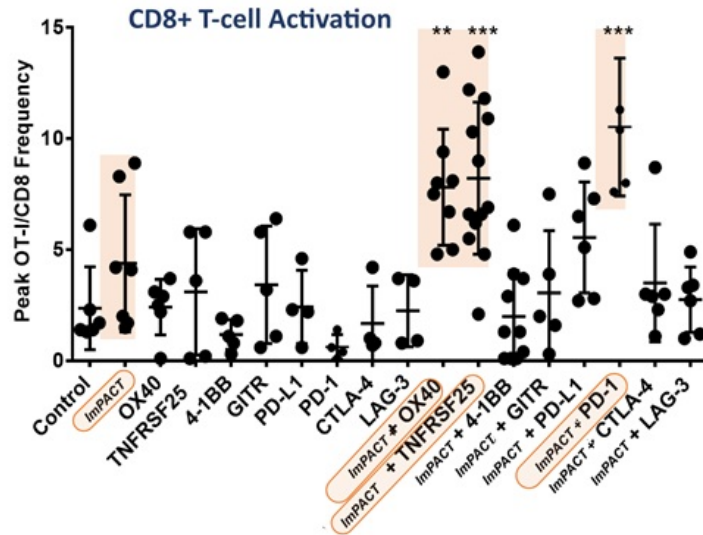
- ✓ Ready-to-use / off-the-shelf
- ✓ Nothing extracted
- ✓ Scalable manufacturing
- ✓ Lower cost of production than autologous cell therapies
- ✓ Intradermal injection

ELISPOT Activity and Survival



Pre-clinical Data

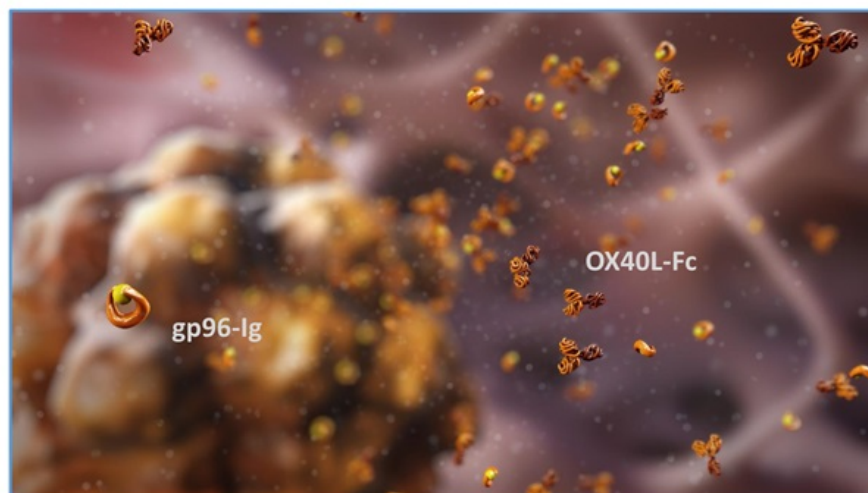
Strong supporting pre-clinical data



- Higher T-cell responses observed in mice treated with *ImpACT* alone
- *ImpACT*® boosted CD+ T-cells to even higher levels when combined with co-stimulator agonist antibodies: OX40, TNFRSF25, PD-1
- Findings suggest synergies when combining *ImpACT* with Pelican's TNFRSF25 antibody

Source: Fromm et al. Society for Immunotherapy of Cancer Annual Meeting, 2016

ComPACT™ Platform Technology

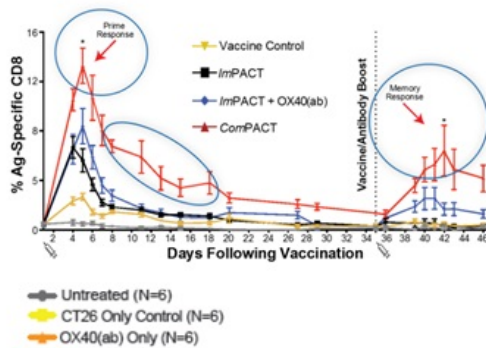


The first potential dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product – combination therapy without additive costs

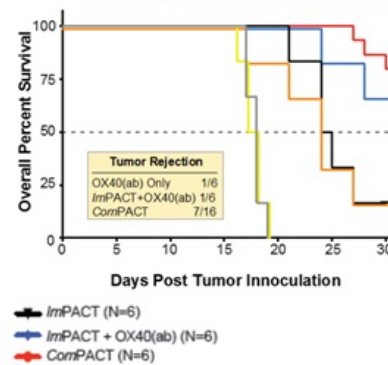
ComPACT™ Outperforms OX40

Monoclonal Antibodies in Pre-clinical Models

Superior primary and memory T-cell response in mouse model



Translates into increased overall survival and tumor reduction in a mouse tumor model

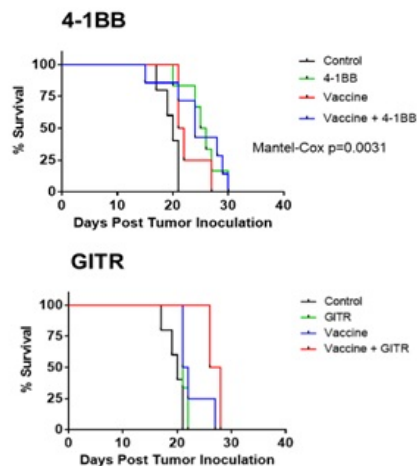


ComPACT generates ~50% complete tumor rejection compared to ~16% with OX40 agonist antibody combinations

PTX-35 Comparative Pre-clinical Anti-tumor Activity

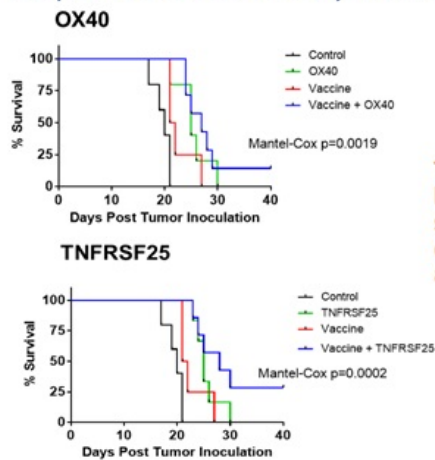
Activity of agonists TNFRSF25, 4-1BB, OX40 and GITR during nine-day B16-F10 melanoma model

4-1BB and GITR agonists have a moderate impact on survival



Schreiber T. et al. SITC 2014

TNFRSF25 agonist leads to markedly increased survival compared to other co-stimulatory antibodies

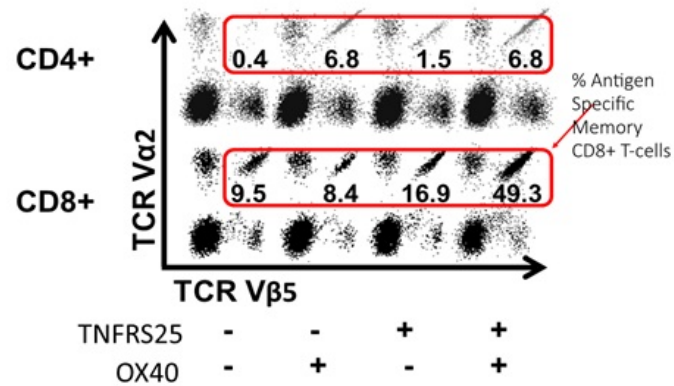


TNFRSF25 agonists leads to increased survival compared to other co-stimulatory antibodies

Preferential CD8+ T-cell Induction with TNFRSF25

Pre-clinical studies with murine agonist antibody shows preferential CD8+ T-cell Induction; differentiation from other T-cell co-stimulators

The frequency of antigen-specific memory CD4+ or memory CD8+ T-cells following treatment of mice with *ImPACT™* alone, or in combination with OX40 or TNFRSF25 antibodies



TNFRSF25 preferentially 'boosts' CD8+ T-cell immunity, whereas OX40 is preferential to CD4+ T-cells

Schreiber et al. *J Immunol* 2012;189(7):3311-8

Emerging Target in T-cell Co-stimulation

Many companies are pursuing co-stimulators with less specificity for CD8+ “memory” activation

Target	Agonist to Target	Clinical Stage	Company	Comments
4-1BB	PF-05082566 (utomilumab)	Phase 1/2 in solid tumors; Phase 3 with quadruple combination B-cell lymphoma	Pfizer	Phase 3 combination 4-1BB+epigenetic modulator+CD20 mAb and/or chemotherapy in refractory B-cell lymphoma
	BMS-663513 (urelumab)	Phase 1/2 in refractory metastatic melanoma	BMS	Combinations with PD-1 inhibitor
CD27	CDX-1127 Anti-CD27	Phase 1/2 combination with checkpoint Pre-clinical	Celldex/BMS Merck/Aduro	Advanced refractory solid tumors; kidney cancer (sunitinab) Shows synergy with checkpoint inhibitors
OX40	MEDI0562 (tavolimab)	Phase 1/2 in advanced solid tumors	MedImmune/A	Combination with PD-L1 (durvalumab); CTLA-4 (tremelimumab)
	GSK3174998	Phase 1/2 in advanced solid tumors	Z	Combination with PD-1 (Keytruda®) in advanced tumors
	INCAGN01949	Phase 1/2 in advanced solid tumors	GSK	Double/triple combinations: PD-1 and CTLA4; IgG1
	MOXR0916	Phase 1/2 in advanced solid tumors	Incyte	Combination with PD-L1 inhibition
	PF-04518600	Phase 1/2 in metastatic kidney cancer	Genentech	Combination with Inlyta® (tyrosine kinase inhibitor); NCI and USC collaboration
GITR	ABBV-368	Phase 1/2 in advanced solid tumors	Pfizer	Phase 2 planned in head/neck + nivolumab
	GWN323	Phase 1	AbbVie	
	INCAGN01876	Phase 1 advanced tumors	Novartis	Advanced tumors/lymphomas: planned combination studies, including PD-1
	MEDI1873	Phase 1 advanced tumors	Incyte/Agenus	MoA involves Treg ADCC + co-stimulation
	TRX-518	Phase 1 advanced tumors	MedImmune/A	Hexameric GITR ligand
ICOS	JTX-2011	Phase 1/2	Z Leap Therapeutics	Fc disabled. Modulates Tregs and T-effector cell ratio
TNFRSF25	PTX-35	IND filing Q4 2018	Celgene/Jounce	Advanced solid tumors
			Heat-Pelican	Advanced solid tumors

Only Pelican is targeting TNFRSF25, an emerging target in immuno-oncology

Expression of T-cell Co-stimulators

TNFRSF25 is preferentially expressed on CD8+ T-cells compared to other T-cell co-stimulators

