
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): **March 6, 2018**

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(b) 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 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 months. 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 Report 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 Report or any of the Exhibits.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Heat Biologics, Inc. investor presentation dated March 2018



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: March 6, 2018

HEAT BIOLOGICS, INC.

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

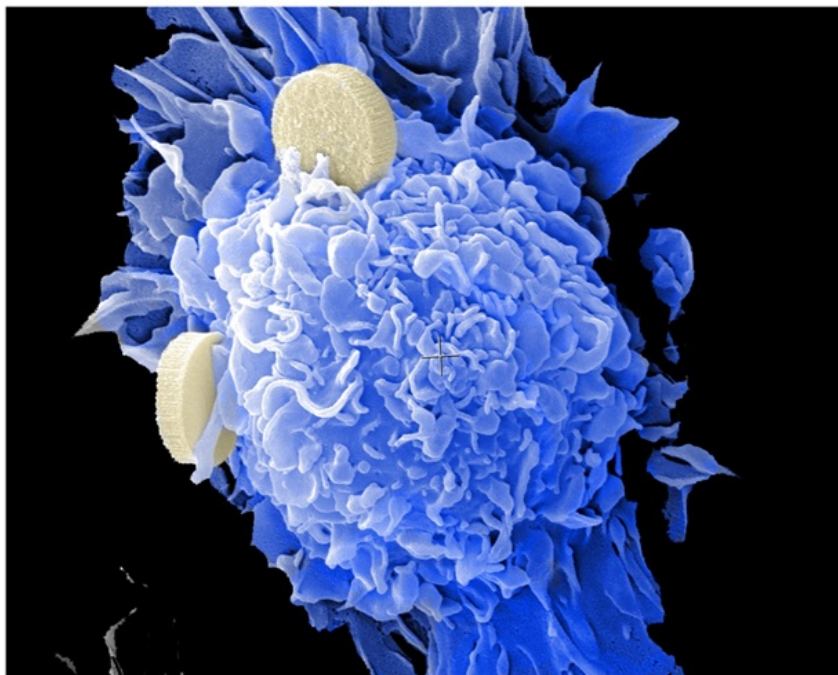
EXHIBIT INDEX

Exhibit No.	Description
99.1	Heat Biologics, Inc. investor presentation, dated March 2018



Heat Biologics

Corporate Presentation
March 2018



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.

Investment Opportunity



Potential Best-in-Class

Activation of CD-8+ cancer killing T-cells



Combination Therapies

Robust pipeline of Combination Therapies



Diverse Technologies

Multiple platform technologies



Checkpoint Inhibitors

Signals in lung cancer with checkpoint inhibitors



Safety Profile

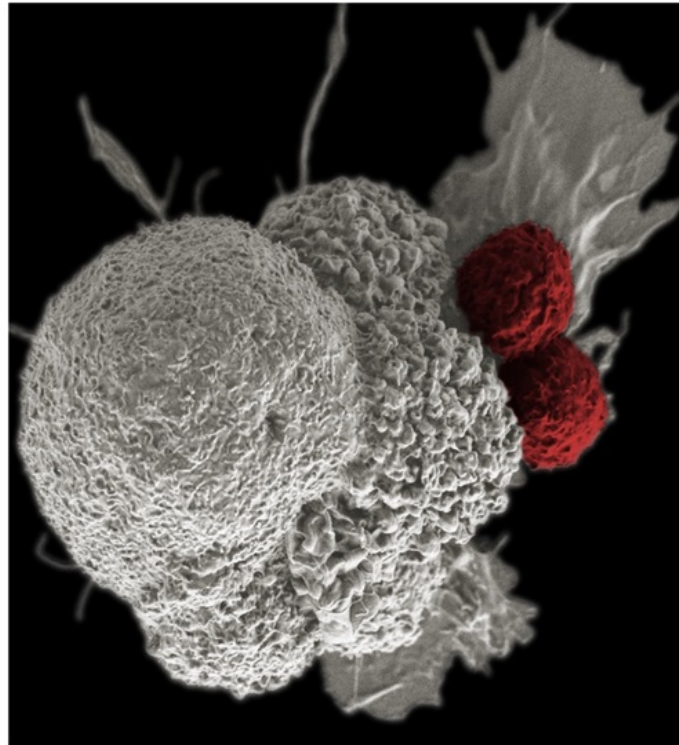
Favorable safety profile

*We turn **COLD** tumors **HOT***

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

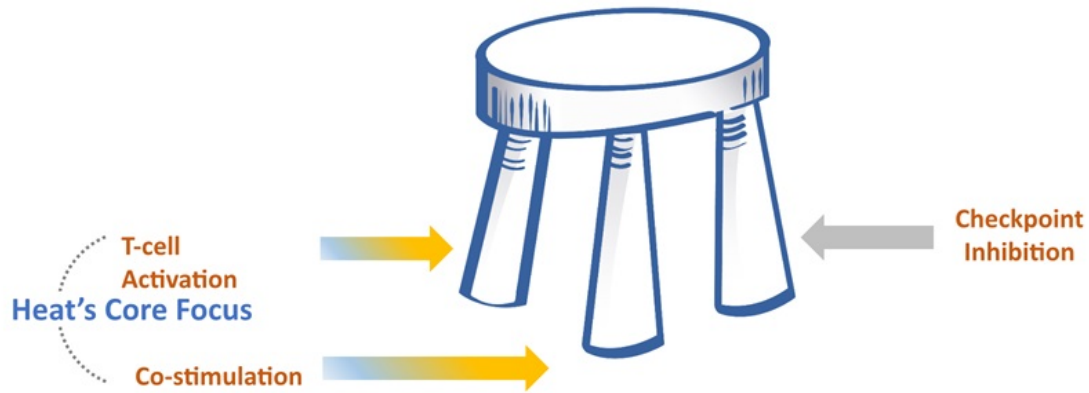




HOT tumors are associated with clinical response

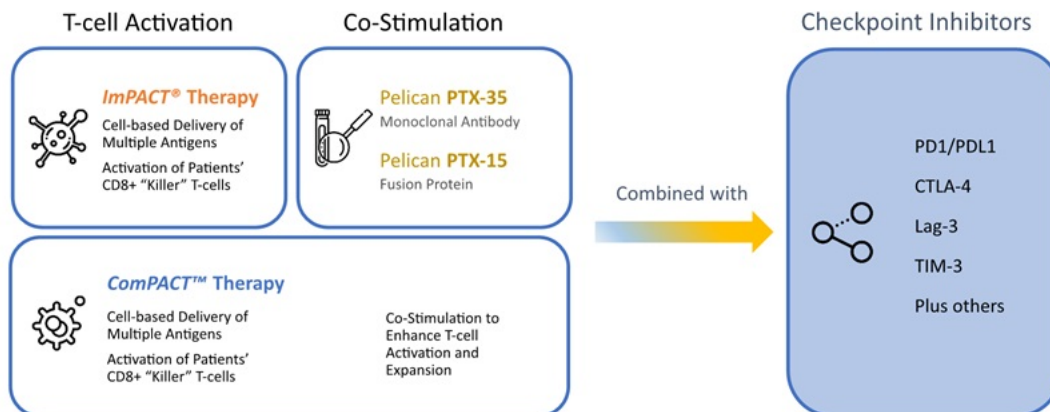
Immuno-Oncology Combination Therapy

The three legs of an Immuno-Oncology Stool

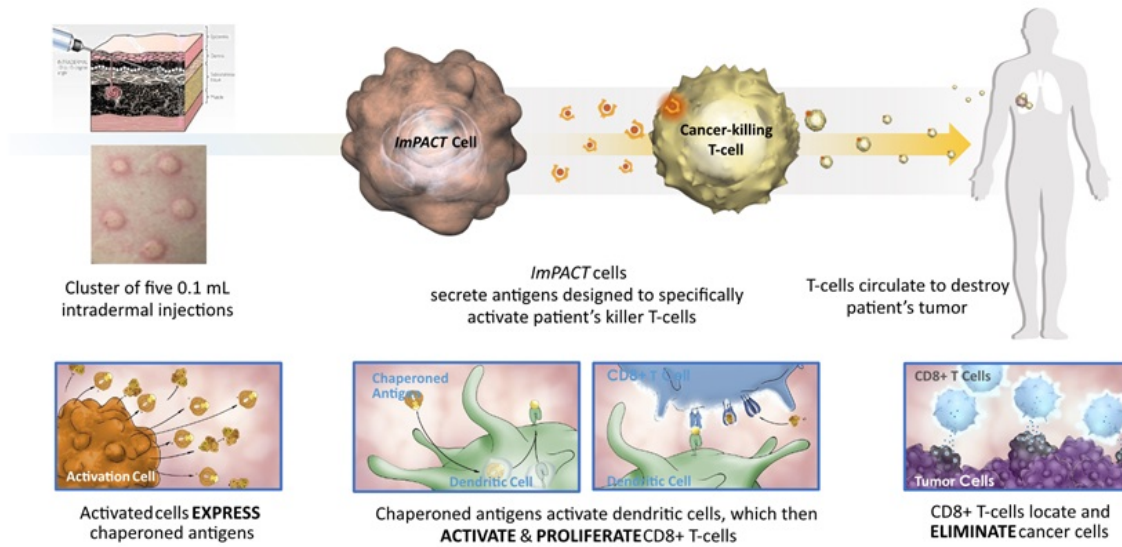


Combination Therapies

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



ImPACT®: Immune Pan-antigen Cytotoxic Therapy



Product Pipeline

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

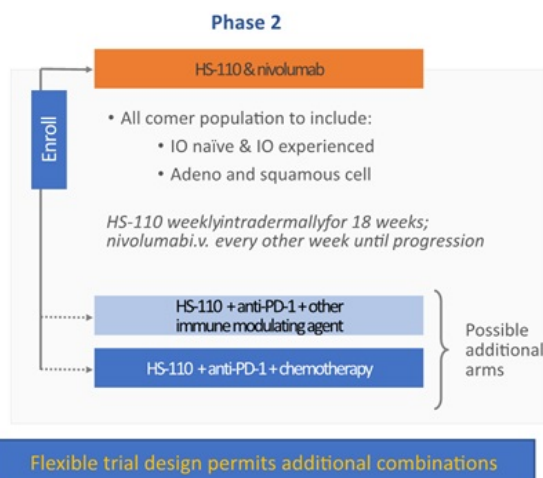
Combination Therapies	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3	Approved	Comments
HS-110 (viagenpumatucl-L)	NSCLC	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	ImPACT® activation technology in combination with nivolumab and other checkpoint inhibitors TBA
HS-120	NSCLC	<div></div>	<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 (\$15.2M CPRIT 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

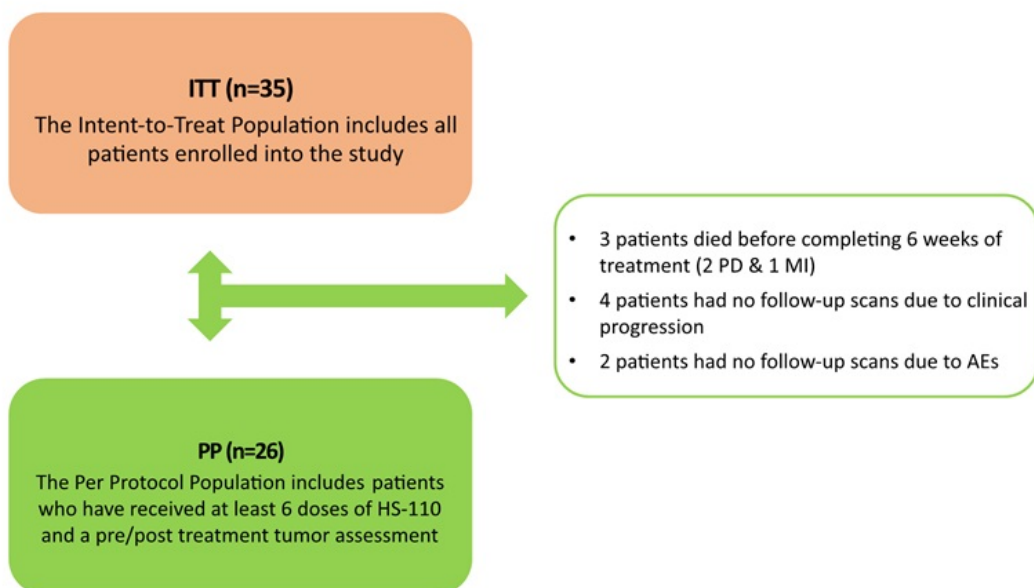
HS-110 (DURGA) Phase 2 Master Protocol: Design

A Phase 1b/2 study of Viagenpumatumel-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 or greater
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



Pre-Specified Patient Populations Analyzed

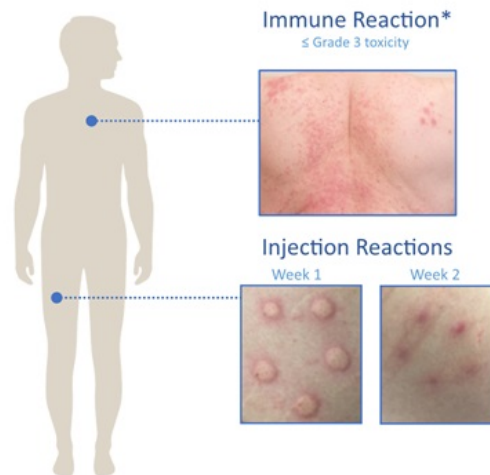


ImPACT (HS-110) Safety Profile to Date

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

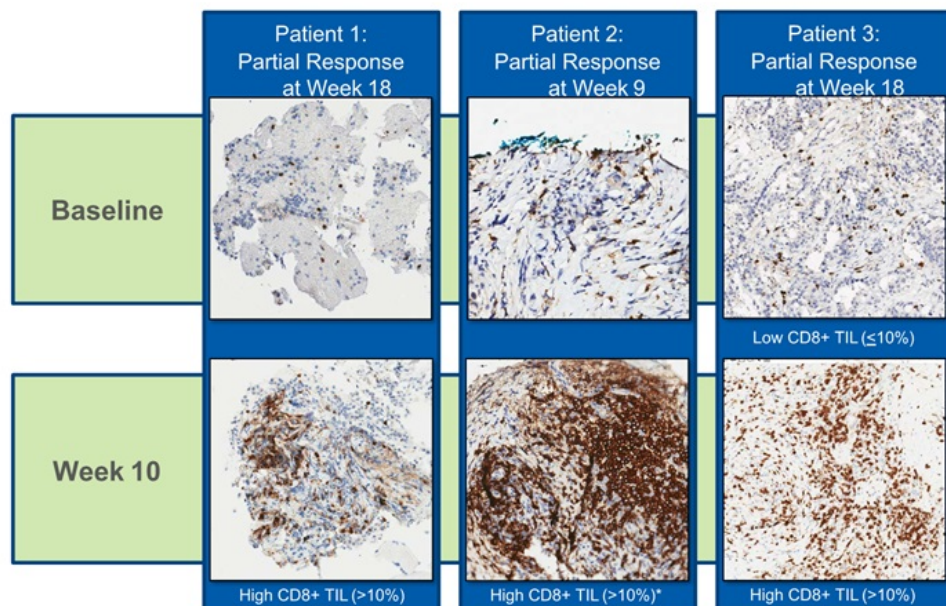
Favorable Safety Profile To Date

- ~1,000 doses administered to ~100 patients
- 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*

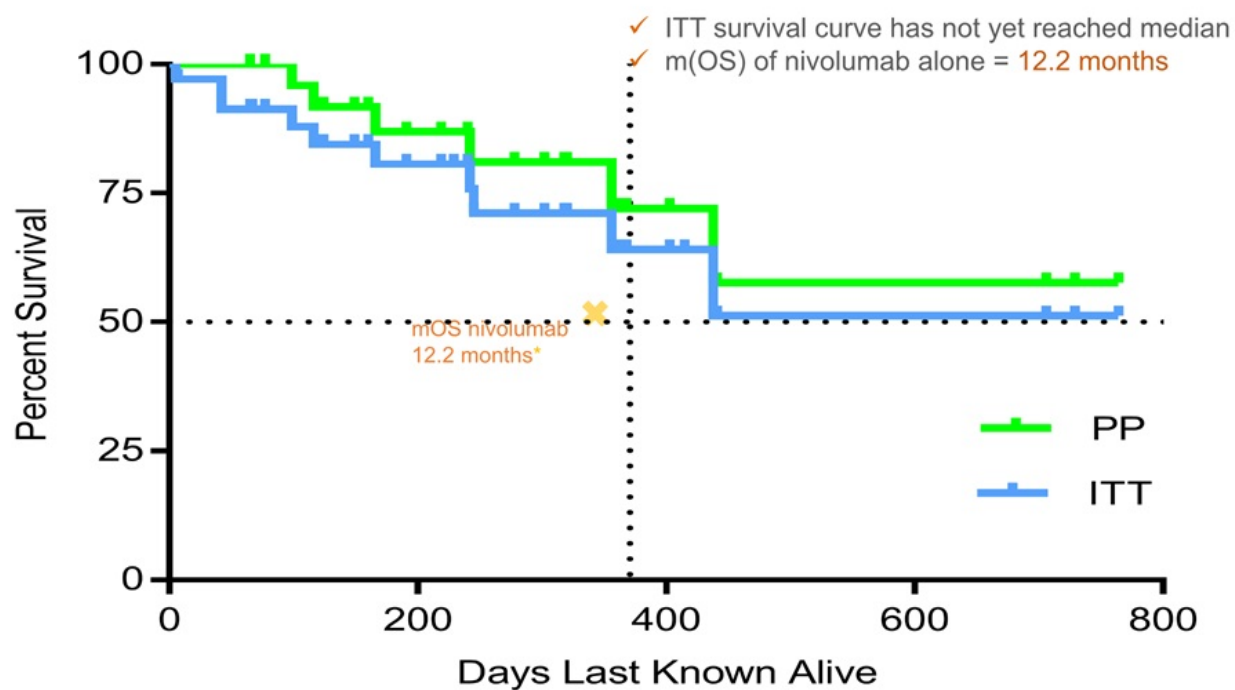
TIL Infiltration Associated with Clinical Response



Clinical evidence that HS-110 is turning COLD tumors HOT

- "Killer" CD8+ T-cells driven deep into tumors
- "Cold" tumors with no previous activation made highly active ("HOT")
- Expression of PD-L1 increased with CD8+ T-cell infiltration in some tumors

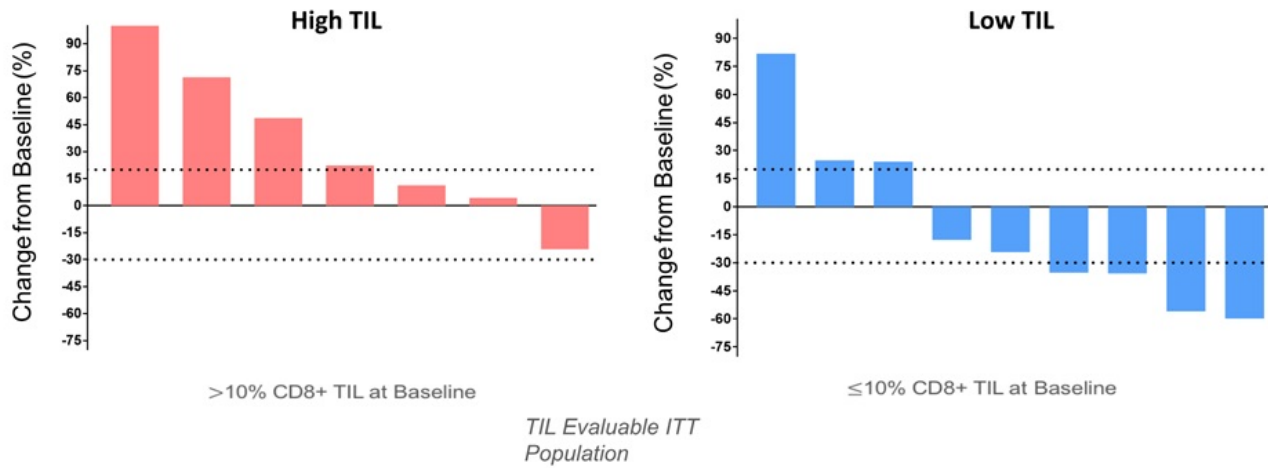
HS-110 Overall Survival



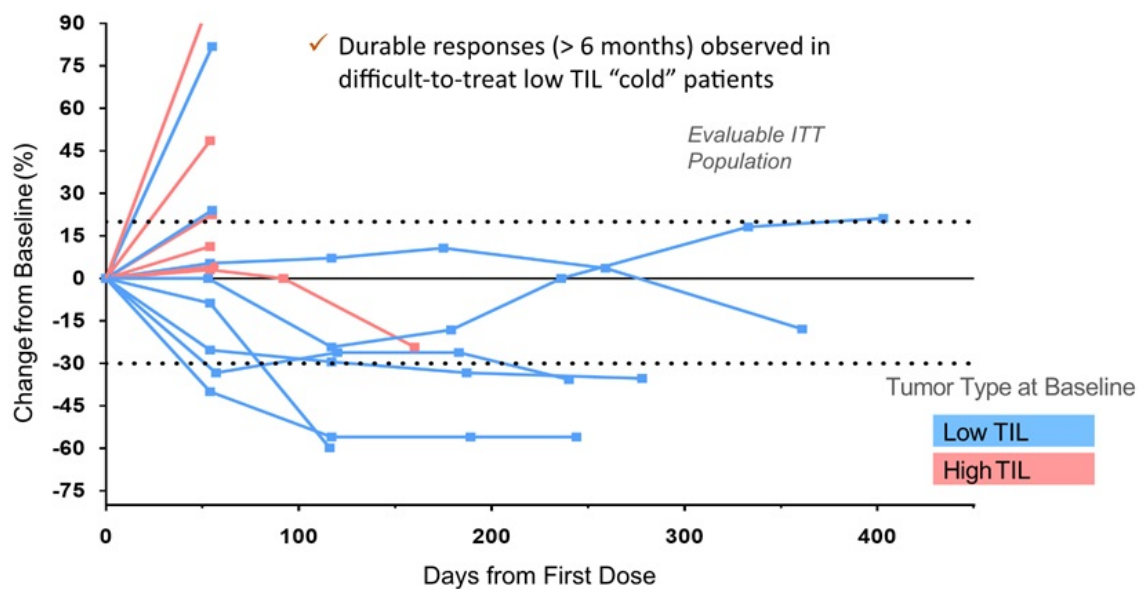
*N Engl J Med 2015; 373: 1627-1639

Target Lesion Response Based on Initial TIL Status

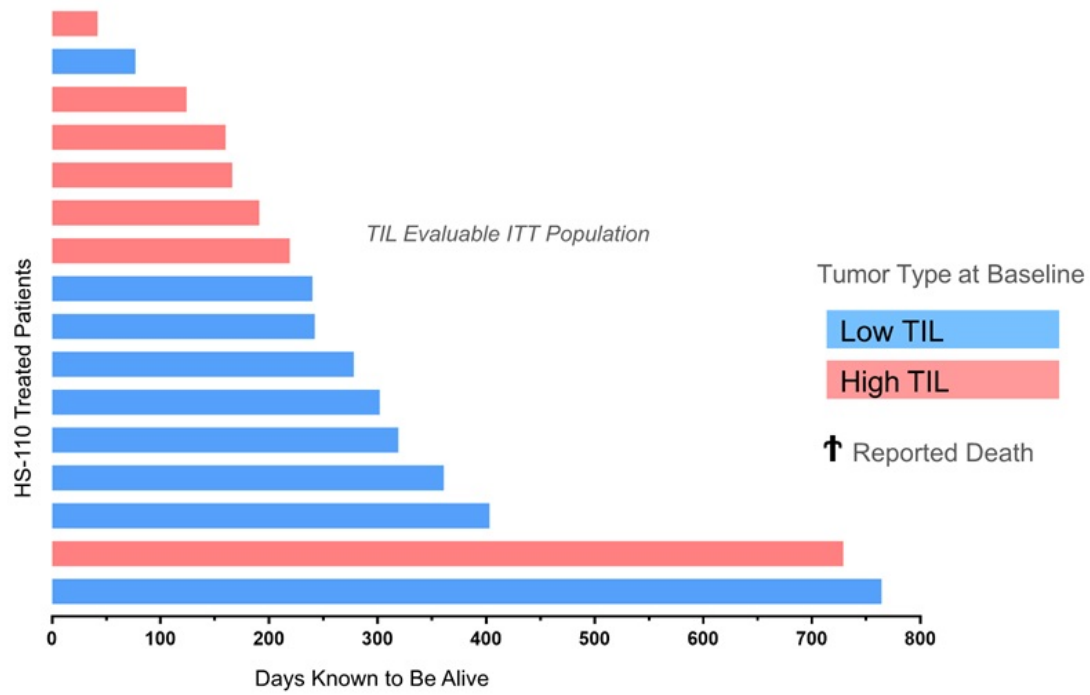
- ✓ HS-110 shows effect in low TIL “cold tumor” patients who typically do not respond well to PD-1 inhibitors
- ✓ 4 of 9 achieved a partial clinical response



Durable Target Lesion Responses Based on Initial TIL Status

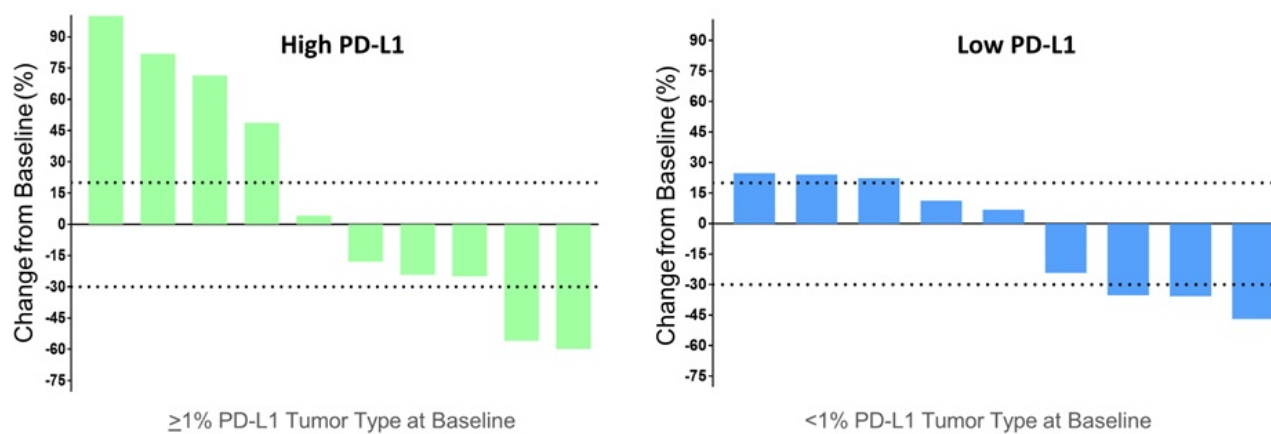


Overall Survival Based on TIL Status



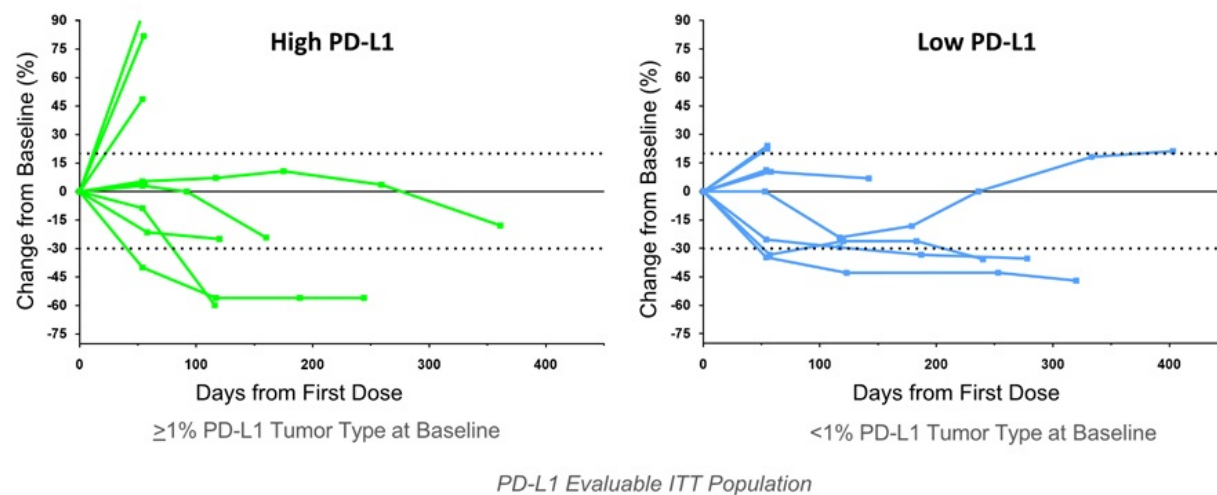
Target Lesion Response Based on Initial PD-L1 Status

- ✓ HS-110 shows effect in low PD-L1 patients who typically do not respond to checkpoint inhibitors

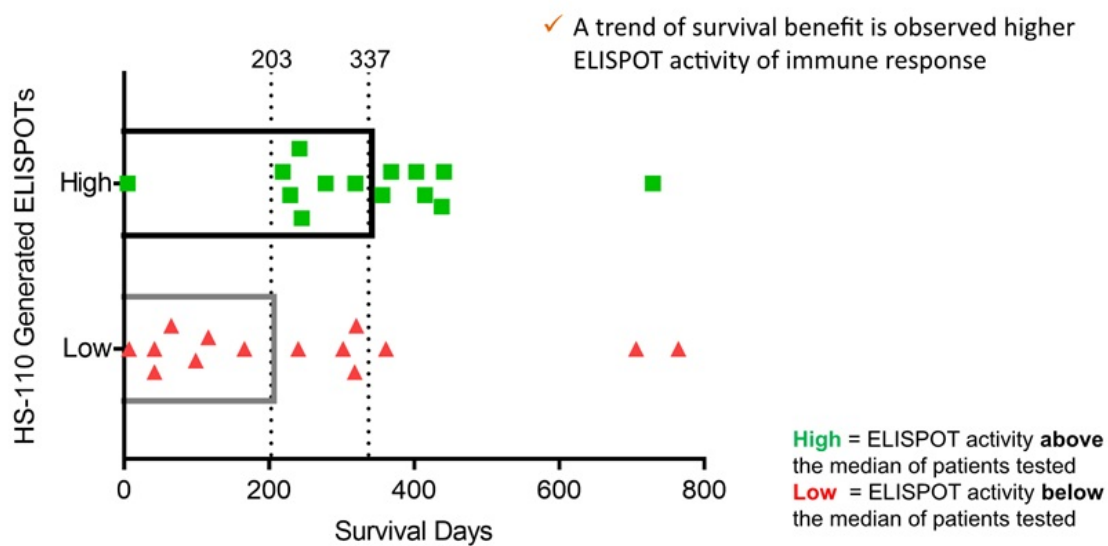


Durable Target Lesion Responses Based on Initial PD-L1 Status

- ✓ Durable responses observed in difficult-to-treat low PD-L1 patients



ELISPOT Activity and Survival



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
 - ✓ While survival data is still maturing, the median overall survival has not yet been reached
- ✓ HS-110 shows durable responses in difficult-to-treat low TIL “cold tumor” patients
- ✓ HS-110 shows durable responses in low PD-L1 patients, who typically do not respond to checkpoint inhibitors
- ✓ A trend of survival benefit is observed with higher ELISPOT activity reflective of tumor antigen-specific immune response

This data is consistent with HS-110 mechanism of action as well as data previously reported in our Phase 1 trial

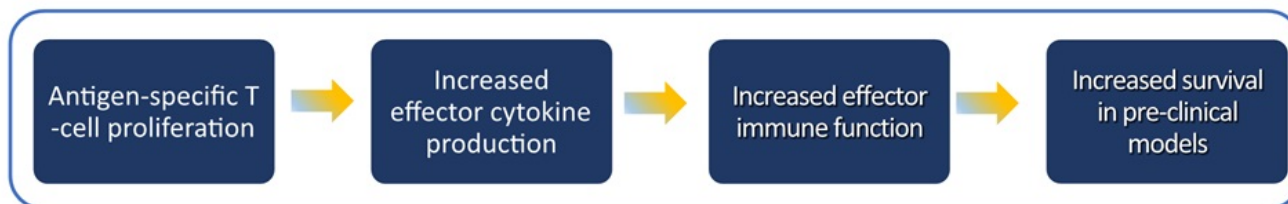
Heat Biologics Acquires Pelican Therapeutics



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

- Heat **acquired 80% controlling interest** in Pelican
- Pelican to operate as a subsidiary in Texas
- 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



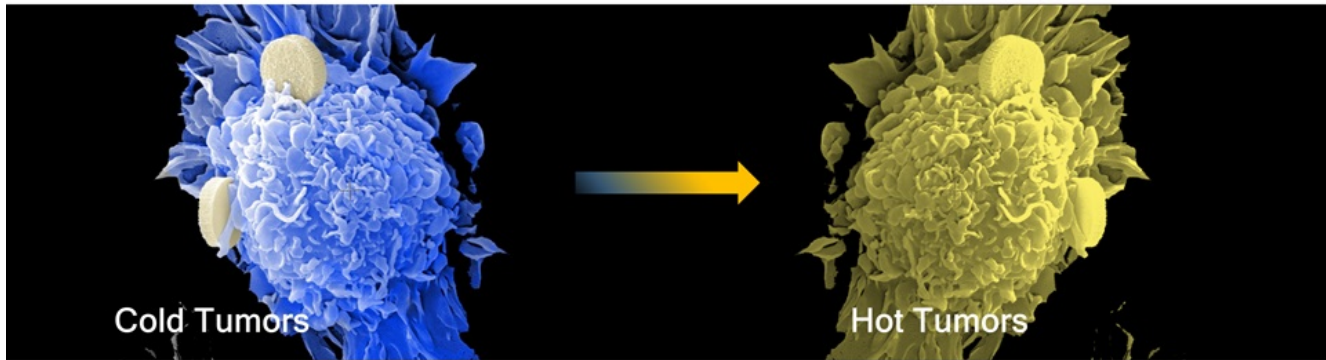
Corporate Highlights

Nasdaq HTBX	Shares Outstanding 4.2M²	Shares Price \$2.38¹
Market Cap \$10M¹	Cash & Equiv. \$9.8M²	Grant Funds \$15.2M

1. Closing price as of March 2, 2018
2. Reported as of December 31, 2017



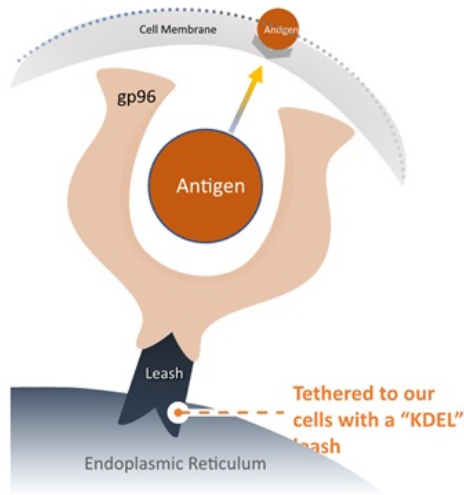
Turning **COLD** Tumors **HOT**



Appendix

Introducing gp96

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



"Molecular Warning System"

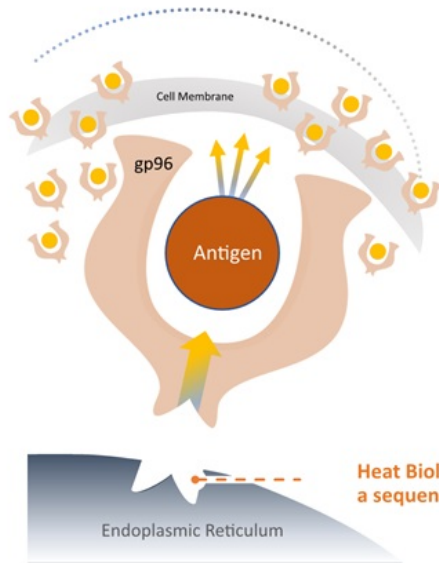
- Natural biological process to deliver proteins (antigens) & gp96 adjuvant to our immune system
- Gp96 "chaperones" newly-created proteins to the cell membrane where they are released and embedded
- Activates a cytotoxic T-cell response to the antigen it is carrying when cells die through necrosis
 - 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

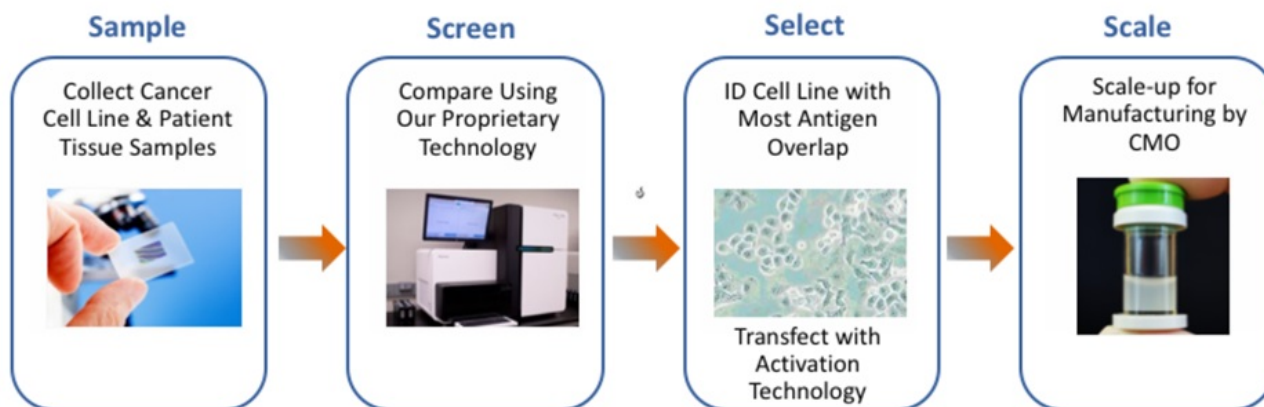


- Genetically modify tumor cells by “severing the leash” that binds the gp96 to the endoplasmic reticulum of the cell and replacing it with a sequence that pumps gp96 out of the cell
- Enables living cancer cells to “pump-out” their own surface antigens along with their gp96 chaperone
 - Mimics necrotic 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[®] 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

Substantial Antigenic Overlap with Patient Tumors

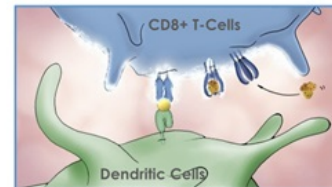
HS-410 selected due to high expression of
>30 shared cancer antigens

>15 antigens also found in
individual patient tumors

Antigen	HS-410
ACTL8	+++
ADAM22	+++
ADAM23	+++
ATAD2	+++
ATAD2B	+++
BIRC5	+++
CASC5	+++
CEP290	+++
CEP55	+++
CTAGE5	+++
DCAF12	+++
DOX5	+++
FAM133A	+++
IL13RA2	+++
IMP3	+++
KIAA0100	+++
MAGEA11	+++
MAGEA3	+++
MAGEA6	+++
MPHOSPH10	+++
OOF2	+++
OOF2L	+++
OP5	+++
PBK	+++
RQCD1	+++
SPAG1	+++
SPAG4	+++
SPAG9	+++
TMEFF1	+++
TTK	+++

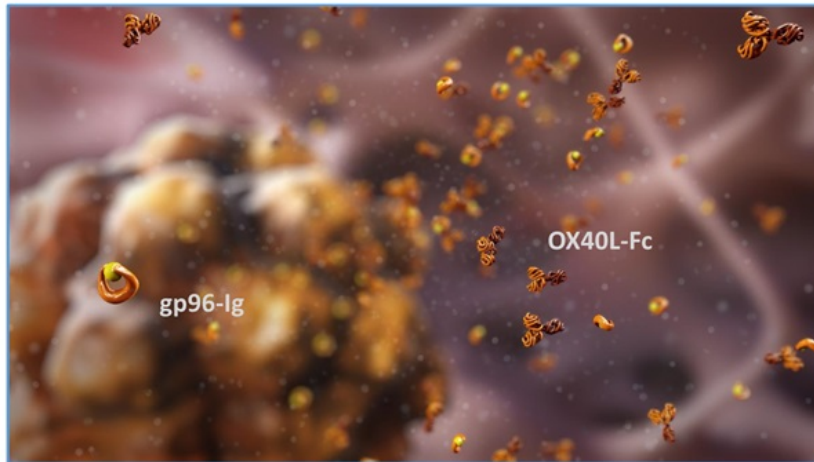
Antigen	23-002	25-001	25-004	25-005	25-003	25-007	25-008
ACTL8	+++	+++	+++	+++	+++	+++	+++
ADAM22	+++	+++	+++	+++	+++	+++	+++
ADAM23	+++	+++	+++	+++	+++	+++	+++
ATAD2	+++	+++	+++	+++	+++	+++	+++
ATAD2B	+++	+++	+++	+++	+++	+++	+++
BIRC5	+++	+++	+++	+++	+++	+++	+++
CASC5	+++	+++	+++	+++	+++	+++	+++
CEP290	+++	+++	+++	+++	+++	+++	+++
CEP55	+++	+++	+++	+++	+++	+++	+++
CTAGE5	+++	+++	+++	+++	+++	+++	+++
DCAF12	+++	+++	+++	+++	+++	+++	+++
DOX5	+++	+++	+++	+++	+++	+++	+++
FAM133A	+++	+++	+++	+++	+++	+++	+++
IL13RA2	+++	+++	+++	+++	+++	+++	+++
IMP3	+++	+++	+++	+++	+++	+++	+++
KIAA0100	+++	+++	+++	+++	+++	+++	+++
MAGEA11	+++	+++	+++	+++	+++	+++	+++
MAGEA3	+++	+++	+++	+++	+++	+++	+++
MAGEA6	+++	+++	+++	+++	+++	+++	+++
MPHOSPH10	+++	+++	+++	+++	+++	+++	+++
OOF2	+++	+++	+++	+++	+++	+++	+++
OOF2L	+++	+++	+++	+++	+++	+++	+++
OP5	+++	+++	+++	+++	+++	+++	+++
PBK	+++	+++	+++	+++	+++	+++	+++
RQCD1	+++	+++	+++	+++	+++	+++	+++
SPAG1	+++	+++	+++	+++	+++	+++	+++
SPAG4	+++	+++	+++	+++	+++	+++	+++
SPAG9	+++	+++	+++	+++	+++	+++	+++
TMEFF1	+++	+++	+++	+++	+++	+++	+++
TTK	+++	+++	+++	+++	+++	+++	+++

This information used to track
T-cells antigen specificity



Source: Heat's HS-410 Phase 1 trial results

ComPACT™ Platform Technology

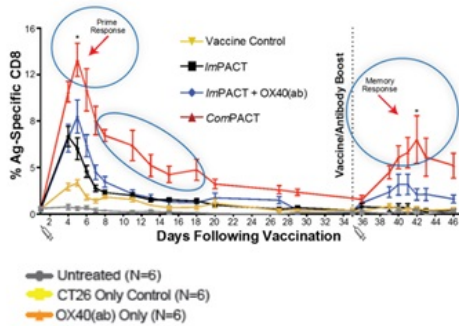


The first potential dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product – combination therapy without additive costs

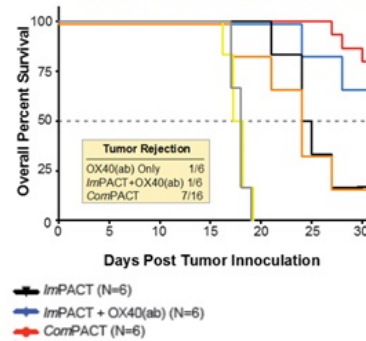
ComPACT™ Outperforms OX40

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

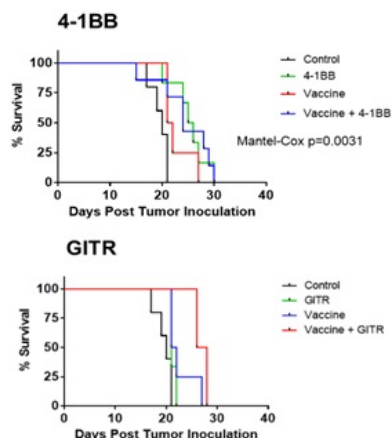


ComPACT generates ~50% complete tumor rejection compared to ~16% with OX40 agonist antibody combinations

PTX-35 Comparative Pre-clinical Anti-tumor Activity

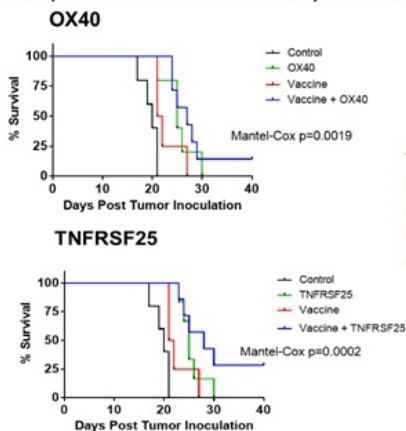
Activity of agonists TNFRSF25, 4-1BB, OX40 and GITR during nine-day B16-F10 melanoma model

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

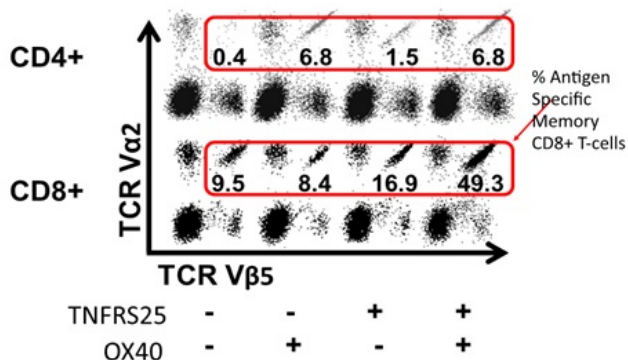


TNFRSF25 agonists leads to increased survival compared to other co-stimulatory antibodies

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

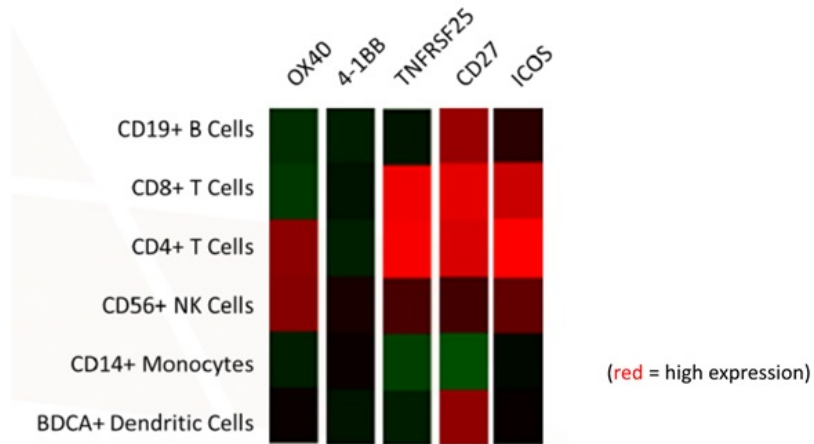
Many companies are pursuing co-stimulators with less specificity for CD8+ “memory” activation

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
	ABBV-368	Phase 1/2 in advanced solid tumors	Pfizer AbbVie	Phase 2 planned in head/neck + nivolumab
GITR	GWN323	Phase 1	Novartis	Advanced tumors/lymphomas: planned combination studies, including PD-1
	INCAGN01876	Phase 1 advanced tumors	Incyte/Agenus	MoA involves Treg ADCC + co-stimulation
	MEDI1873	Phase 1 advanced tumors	MedImmune/A	Hexameric GITR ligand
	TRX-518	Phase 1 advanced tumors	Z Leap Therapeutics	Fc disabled. Modulates Tregs and T-effector cell ratio
ICOS	JTX-2011	Phase 1/2	Celgene/Jounce	Advanced solid tumors
TNFRSF25	PTX-35	IND filing Q4 2018	Heat-Pelican	Advanced solid tumors

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

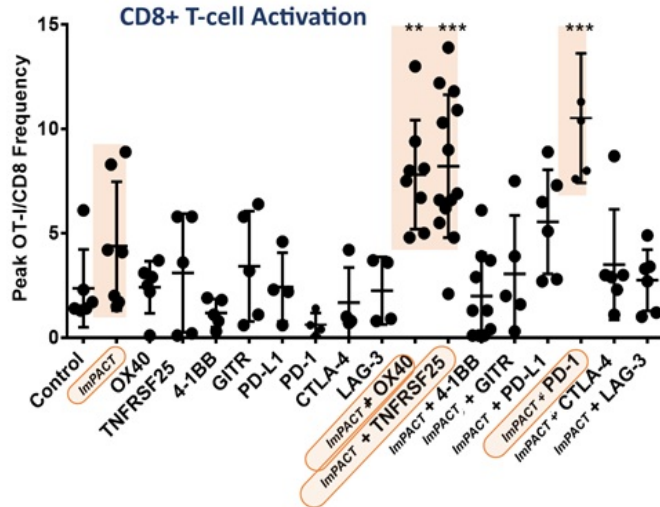
Expression of T-cell Co-stimulators

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



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

Highlights from Pelican Pre-clinical Studies

- ✓ mAb to TNFRSF25:
 - ✓ Drives the development of **antigen-specific CD8+ T-cells** (mimics TL1A, the specific ligand of TNFRSF25)
 - ✓ Equals co-stimulation and expansion of antigen-experienced memory T-cells: CD4+ and CD8+
 - ✓ Significantly enhanced effect on **memory CD8+ T-cells**
 - ✓ Co-stimulation occurs only in the context of **TCR recognition of antigen**
 - ✓ **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**
 - ✓ In mouse melanoma models, TNFRSF25 mAb results in increased survival **compared to agonism of OX40, GITR, 4-1BB** with respective agonist mAbs
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