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): **February 28, 2019**

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware
(State or other jurisdiction of incorporation)

001-35994	**26-2844103**
(Commission File Number)	*(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.

On February 28, 2019, Heat Biologics, Inc. (the "Company") issued a press release announcing updated interim results from its ongoing Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced non-small cell lung cancer (NSCLC) that were presented today at the ASCO-SITC Clinical Immuno-Oncology Symposium by Daniel Morgensztern, M.D., Associate Professor of Medicine and Director of Thoracic Oncology, Washington University School of Medicine, and Lead Investigator in the trial. Data were presented on both Cohort A and Cohort B of the trial. Cohort A enrolls only previously treated patients who have never received a checkpoint inhibitor (CPI), while Cohort B enrolls patients who received a minimum of 4 months of treatment with a CPI as part of their prior therapy, but subsequently had documented progressive disease. Preliminary data suggest that the addition of HS-110 to Nivolumab may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor. Improved survival was observed in patients with low CD8+ "cold" tumor at baseline compared to high CD8+ patients and the occurrence of injection site reactions correlated with improved overall survival.

Highlights for both cohorts are presented below:

Cohort B (patients who progressed after prior treatment with a checkpoint inhibitor)

- Of first 20 patients enrolled in this cohort:
  - Partial response (PR) in 3 patients (15%) per RECIST 1.1 and 4 patients (20%) per investigator assessment
  - Stable disease (SD) in 8 patients (40%)
  - Disease control rate (DCR) of 55%
- The 3 RECIST 1.1 PR patients had documented progression on a CPI immediately preceding study entry.
- Median progression free survival (mPFS) was 2.7 months (95% CI; 1.8 - 4.0 months).

Cohort A (patients who have never received a CPI prior to study entry)

- Of 42 patients enrolled by the cutoff date:
  - PR in 9 patients (21%) per RECIST 1.1
  - SD in 12 patients (29%)
  - DCR of 50%
  - Median overall survival not yet reached (60% still alive with a median follow-up of 14.4 months)
- Responses and disease stabilization are durable and long-lasting.
- Subgroup analyses, predefined in the clinical protocol, were performed for levels of tumor-infiltrating lymphocytes (CD8+ TILs) present in tumors at baseline. There was evidence of a survival benefit (HR = 0.39) in patients with levels CD8+ TIL $\leq$10% (i.e. "cold" tumors), a population that typically responds poorly to checkpoint inhibitors. The treatment benefit appeared to be independent of PD-L1 status (HR = 0.85).
- Immune reactivity to HS-110 was measured via ELISPOT assay (high vs. low compared to median) on patient peripheral blood mononuclear cells obtained before and during treatment with a median overall survival benefit of 6.2 months in the high ELISPOT group.
- Overall survival was significantly higher in patients that experienced at least one dermal injection site reaction to HS-110 at any time during study treatment, supporting HS-110's mechanism of action (HR= 0.15 [95% CI: 0.05-0.45], p=0.0001).

For both cohorts, treatment with HS-110 in combination with nivolumab was well tolerated, with no additional toxicities beyond those observed with single agent CPI therapy.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

A copy of the Company's revised corporate presentation that includes the interim results set forth above is attached as Exhibit 99.2 hereto, which is incorporated herein by reference.

The slide presentation attached as Exhibit 99.2 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 Current Report or any of the Exhibits.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed with this Current Report on Form 8-K:

Exhibit Number	Description
99.1	Press Release of Heat Biologics, Inc. dated February 28, 2019
99.2	Heat Biologics, Inc. Investor Presentation

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: February 28, 2019

HEAT BIOLOGICS, INC.

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

EXHIBIT INDEX

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EXHIBIT 99.1

Heat Biologics Presents Interim Phase 2 Lung Cancer Data on HS-110 + Nivolumab at ASCO-SITC Clinical Immuno-Oncology Symposium

Preliminary data suggests the addition of HS-110 to Nivolumab may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor therapy

Median overall survival not yet reached with median follow up of 14.4 months in Cohort A

Improved survival observed in patients with low CD8+ "cold" tumor at baseline compared to high CD8+ patients

Occurrence of injection site reactions correlates with improved overall survival

San Francisco, CA – February 28, 2019 – Heat Biologics, Inc. (NASDAQ: HTBX), a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer, today announced updated interim results from its ongoing Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced non-small cell lung cancer (NSCLC). The results were presented today at the ASCO-SITC Clinical Immuno-Oncology Symposium by Daniel Morgensztern, M.D., Associate Professor of Medicine and Director of Thoracic Oncology, Washington University School of Medicine, and Lead Investigator in the trial. Data were presented on both Cohort A and Cohort B of the trial. Cohort A enrolls only previously treated patients who have never received a checkpoint inhibitor (CPI), while Cohort B enrolls patients who received a minimum of 4 months of treatment with a CPI as part of their prior therapy, but subsequently had documented progressive disease.

"The treatment landscape for NSCLC has fundamentally changed as the number of patients who receive first line checkpoint inhibitor therapy is rapidly increasing," said COL(ret) George E Peoples, MD, FACS, Heat's Chief Medical Advisor. "The preliminary data from our Cohort B is increasingly relevant and potentially exciting as it suggests that the addition of HS-110 to nivolumab may restore anti-tumor activity in patients whose disease has progressed after treatment with a CPI."

Jeff Hutchins, Ph.D., Chief Scientific and Operating Officer of Heat said, "The observed response rates and durability of disease stabilization support our mechanistic hypothesis that the broad, T-cell mediated immune response activated by HS-110 may improve patient survival when administered in combination with a CPI. The Cohort B data suggest that HS-110 may improve clinical outcomes for patients who have lost the benefit of treatment with a checkpoint inhibitor. We look forward to completing enrollment in this trial in Q2 and releasing additional results later this year as the data matures."

Highlights for both cohorts are presented below:

Cohort B (patients who progressed after ≥ 4 months of prior treatment with a checkpoint inhibitor)

- Of first 20 patients enrolled in this cohort:
  - Partial response (PR) in 3 patients (15%) per RECIST 1.1 and 4 patients (20%) per investigator assessment
  - Disease control rate (DCR) of 55%
- The 3 RECIST 1.1 PR patients had documented progression on CPI monotherapy immediately preceding study entry
- Median progression free survival (mPFS) was 2.7 months (95% CI; 1.8 - 4.0 months)

Cohort A (patients who have never received a CPI prior to study entry)

- Of 42 patients enrolled by the cutoff date:
  - PR in 9 patients (21%) per RECIST 1.1
  - DCR of 50%
  - Median overall survival not yet reached (60% still alive with a median follow-up of 14.4 months)
- Responses and disease stabilization are durable and long-lasting
- Subgroup analyses, predefined in the clinical protocol, were performed for levels of tumor-infiltrating lymphocytes (CD8+ TILs) present in tumors at baseline. A survival benefit [hazard ratio (HR) = 0.39] was observed in patients with levels CD8+ TIL <10% (i.e. “cold” tumors), a population that typically responds poorly to checkpoint inhibitors. The treatment benefit appeared to be independent of PD-L1 status (HR = 0.85)
- Immune reactivity to HS-110 was measured via ELISPOT assay (high vs. low compared to median) on patient peripheral blood mononuclear cells obtained before and during treatment with a median overall survival benefit of 6.2 months in the high ELISPOT group
- Overall survival was significantly higher in patients that experienced at least one dermal injection site reaction to HS-110 at any time during study treatment, supporting HS-110’s mechanism of action (HR = 0.15 [95% CI: 0.05-0.45], p=0.0001)

For both cohorts, treatment with HS-110 in combination with nivolumab was well tolerated, with no additional toxicities beyond those observed with single agent CPI therapy.

Importantly, data from Cohort B suggest that HS-110 in combination with nivolumab reduced tumor burden in patients whose disease progressed after treatment with a checkpoint inhibitor at any time prior to study entry. Additionally, the deepest responses were observed in three patients whose last treatment immediately preceding enrollment was checkpoint inhibitor monotherapy.

Also of interest is the data regarding overall survival (OS) in patients with low CD8+ TIL (tumor infiltrating lymphocytes) at baseline. Protocol-defined subgroup analysis of patients categorized as 'high' or low' TIL, based on levels of CD8+ cells present in the stroma of their tumor tissue at baseline, demonstrate a survival advantage for the 'low TIL' group as compared to the 'high TIL' group (not reached vs. 13.8 months; HR = 0.39 [95% CI; 0.06-2.31]. These data are very encouraging as prior studies with nivolumab alone suggest that "cold" tumor patients with lower levels of baseline CD8+ TILs have lower response rates compared to "hot" tumor patients with high levels of CD8+ TILs[1].

Trial results are summarized in the company's updated corporate presentation, along with the official ASCO-SITC poster.

Trial Design

The Phase 2 trial is designed to evaluate the safety and efficacy of HS-110 combined with an immune checkpoint inhibitor for the treatment of advanced non-small cell lung cancer. Patients receive weekly HS-110 (1×10^7 cells) administered as 5 intradermal 0.1 mL injections for 18 weeks in combination with bi-weekly nivolumab 240 mg IV administered until confirmed disease progression or unacceptable toxicity, whichever occurs first. The primary endpoint is objective response rate (ORR); secondary endpoints include overall survival (OS), progression-free survival (PFS), disease control rate (DCR) and duration of response (DOR). Exploratory endpoints include correlation of clinical outcomes to baseline CD8+ TILs, PD-L1 expression, peripheral blood tumor mutation burden and ELISPOT analysis.

For further details about the trial and the results presented at ASCO-SITC, refer to Heat Bio's updated corporate presentation, which can be found on the Investors tab of the corporate website https://ir.heatbio.com/.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using of CD8+ "Killer" T-cells. Our T-Cell Activation Platform ("TCAP") produces therapies designed to turn "cold" tumors "hot" and be administered in combination with checkpoint therapies and other immuno-modulators to increase their effectiveness. HS-110 is our first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Our *ComPACT* technology is the first potential, dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product. We are currently enrolling patients in our Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®) and with Merck's pembrolizumab (Keytruda®). Pelican Therapeutics, a subsidiary of Heat, is focused on the development of co-stimulatory monoclonal antibody and fusion protein-based therapies designed to activate the immune system. For more information, please visit www.heatbio.com.

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[1] S Sahba A-L. Niemeijer J. De Langen E. Thunnissen, *Annals of Oncology*, Volume 28, Issue suppl 5, September 1, 2017

Forward Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 on our current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based upon current beliefs, expectation, and assumptions and include statements regarding the suggestion that the addition of HS-110 to Nivolumab may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor and the suggestion that HS-110 may improve clinical outcomes for patients who have lost the benefit of treatment with a checkpoint inhibitor. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's therapies to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, Heat's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Heat's ability to promote or commercialize its product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products, Heat's ability to maintain its license agreements, the continued maintenance and growth of its patent estate, its ability to establish and maintain collaborations, its ability to obtain or maintain the capital or grants necessary to fund its research and development activities, and its ability to retain its key scientists or management personnel, and the other factors described in Heat's filings with the SEC. The information in this release is provided only as of the date of this release, and Heat undertakes no obligation to update any forward-looking statements contained in this release based on new information, future events, or otherwise, except as required by law.

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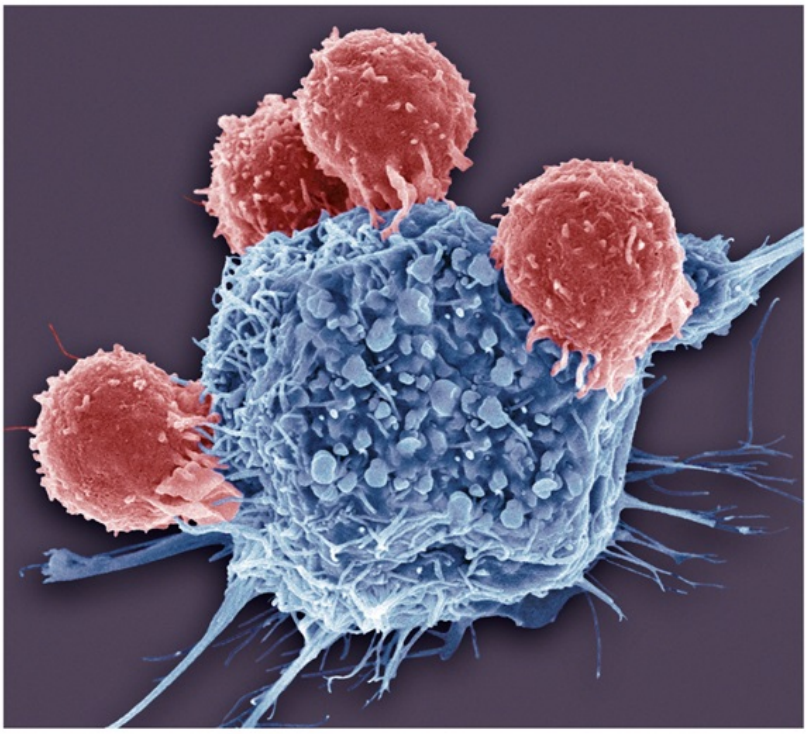
investorrelations@heatbio.com

Heat Biologics

Heat Biologics

Corporate Presentation

February 28, 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.

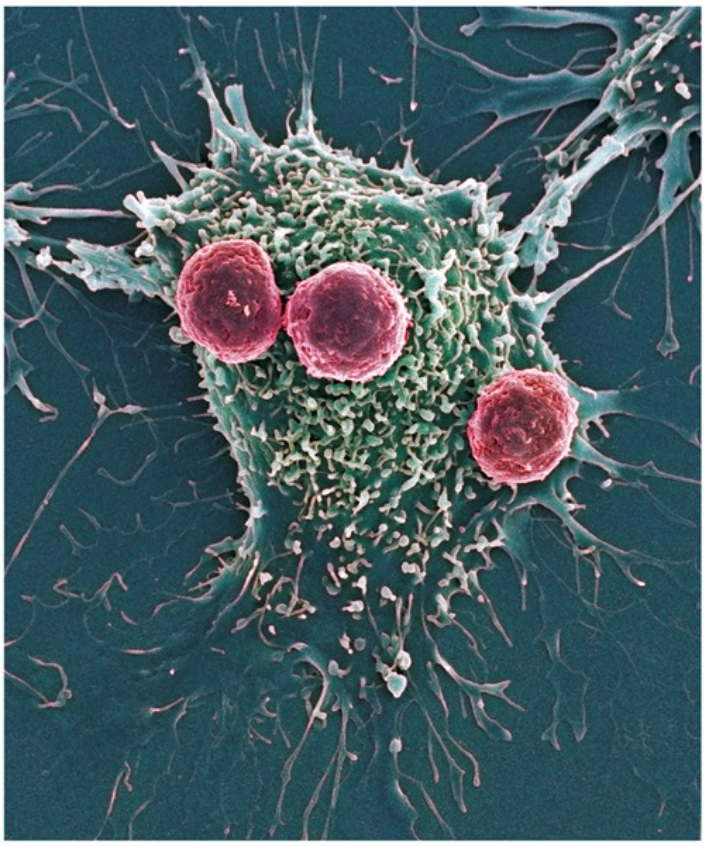
You should read carefully the factors described in the "Risk Factors" sections of our SEC Filings to better understand the risks and uncertainties inherent in our business.

Heat Biologics

Our Mission

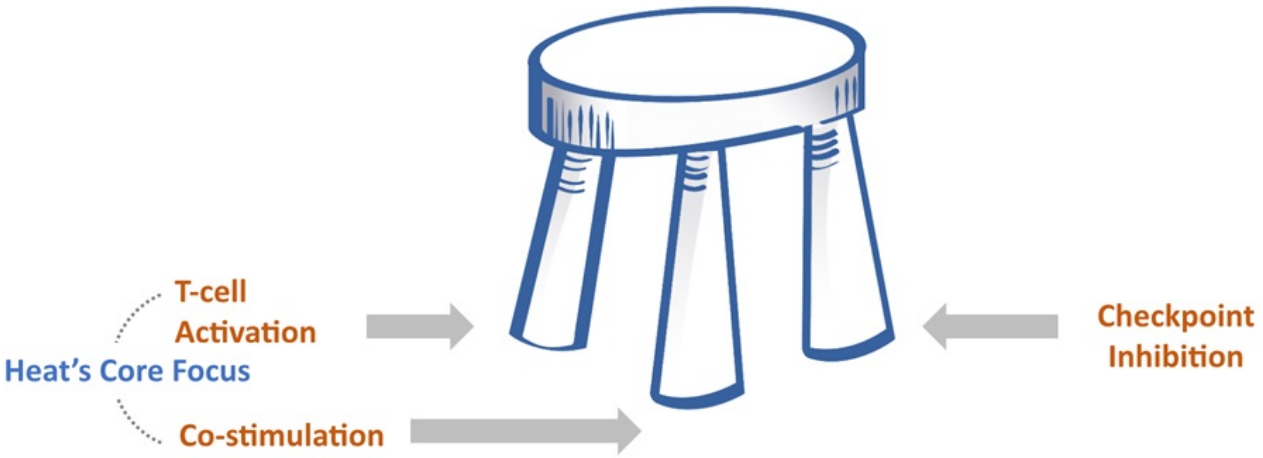
To improve patient outcomes by developing more effective immunotherapies designed to

Turn "COLD" tumors "HOT



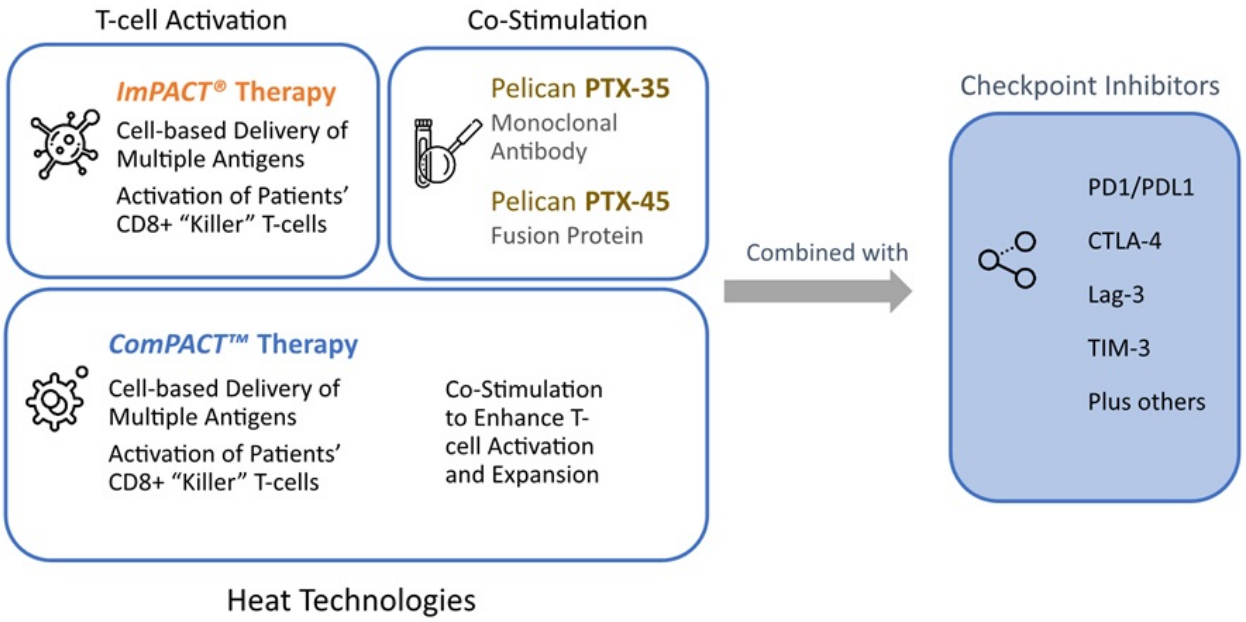
Effective Immuno-Oncology Therapy

The three legs of an Immuno-Oncology Stool



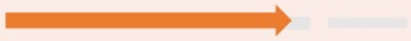
Combination Therapies

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



Product Pipeline

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

Combination Therapies	Indication	Pre-clinical / Phase 1 / Phase 2 / Phase 3	Comments
ImPACT® HS-110	NSCLC		*ImPACT™* activation technology in combination with nivolumab and pembrolizumab
ComPACT® HS-130	Multiple Solid Tumors		*ComPACT™* activation technology in combination with checkpoint inhibitors
Co-stimulators			
PTX-35	Multiple Solid Tumors		Humanized monoclonal antibody, functional agonist of human TNFRSF25 ($15.2M CPRIT grant)
PTX-45	TBA		TL1A-Ig fusion protein, functional agonist of human TNFRSF25

ImPACT® "Off-the-shelf" Manufacturing

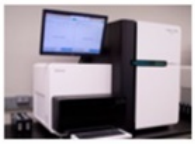
Designed for Robust, Pan-antigen T-cell Activation

Sample

Collect Cancer Cell Line & Patient Tissue Samples

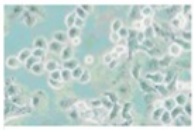
Screen

Compare Using Our Proprietary Technology



Select

ID Cell Line with Most Antigen Overlap



Transfect with Activation Technology

Scale

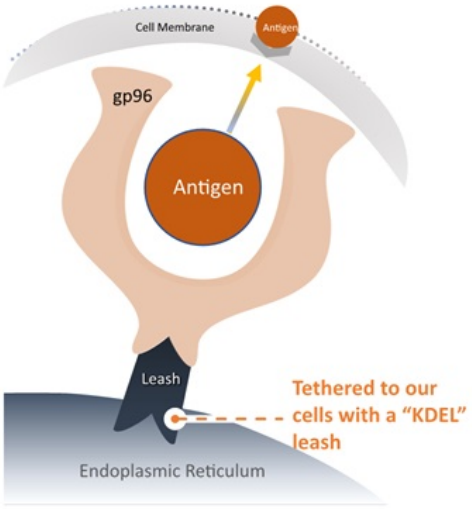
Scale-up for Manufacturing by CMO

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

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

Introducing gp96 – Its dual role

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



"Molecular Warning System"

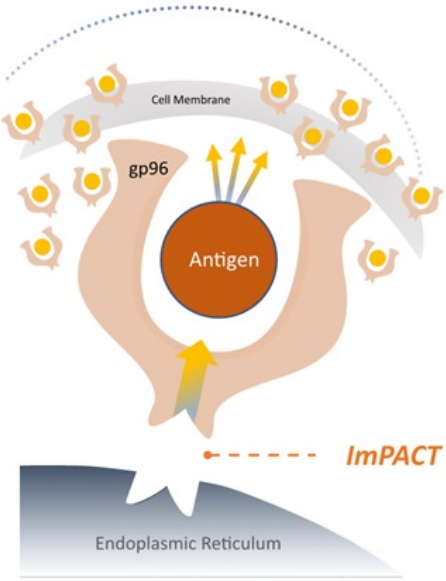
- A natural biological process to deliver proteins (antigens) & gp96 to our immune system
- Gp96 "chaperones" newly-created proteins to the cell membrane where they are released and embedded
- Gp96 chaperoned proteins are only naturally released via necrosis
- Gp96, when present outside the cell, alerts the immune system and then becomes one of the most powerful adjuvants that show exclusive specificity to CD8+ ("killer") T-cells

**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



***ImPACT®* technology** genetically modifies tumor cells by "severing the leash" that binds the gp96 to the endoplasmic reticulum, and replacing it with a secretory sequence that pumps gp96 out of the cell

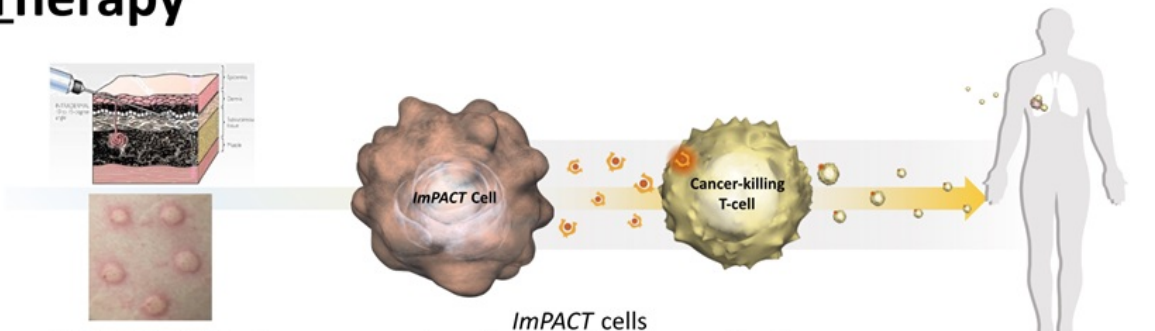
Mimics necrotic cell death by enabling fully-allogeneic "off-the-shelf" living cancer cells to "pump-out" their own antigens along with their gp96 chaperone

***ImPACT* technology removes the leash that binds gp96 to the cell**

Designed to activate a powerful pan-antigen cytotoxic T-cell immune response

Heat Biologics

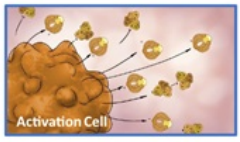
ImPACT®: Immune Pan-antigen Cytotoxic Therapy



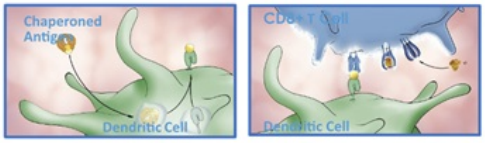
Cluster of five 0.1 mL intradermal injections

ImPACT cells secrete antigens designed to specifically activate patient's killer T-cells

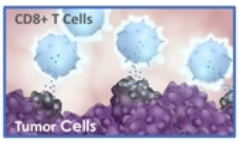
T-cells circulate to destroy patient's tumor



Activated cells **EXPRESS** chaperoned antigens



Chaperoned antigens activate dendritic cells, which then **ACTIVATE** & **PROLIFERATE** CD8+ T-cells



CD8+ T-cells locate and **ELIMINATE** cancer cells

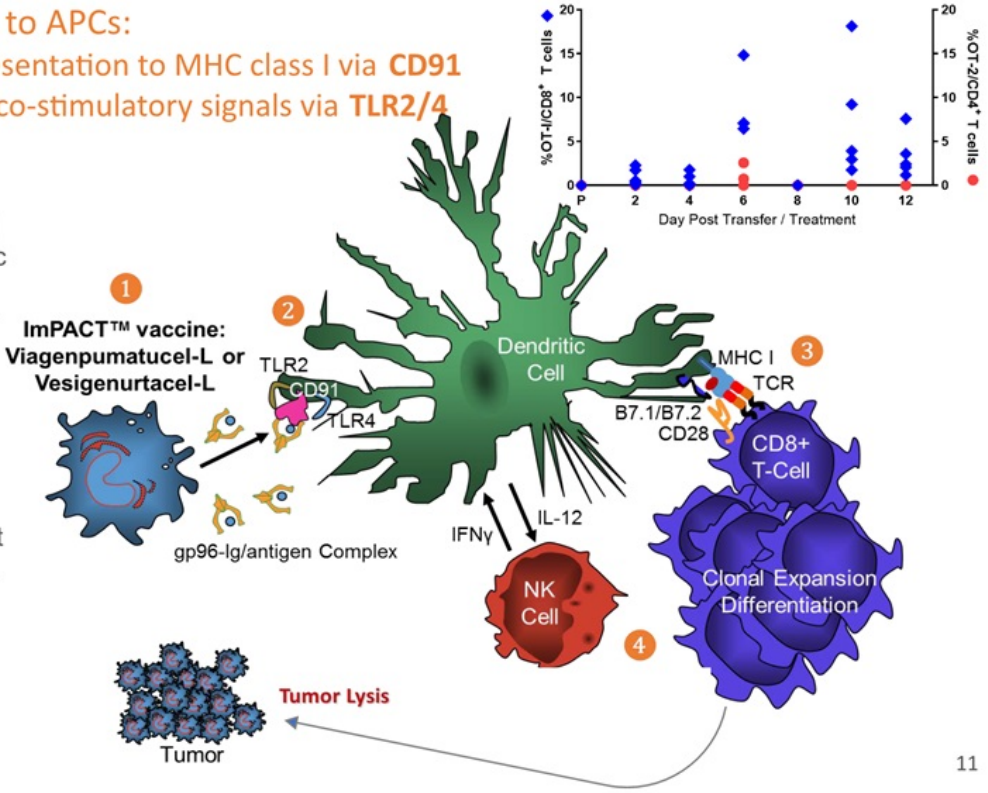
Heat's unique cell-secreted gp96 firstly activates dendritic cells via TLR signaling and subsequently CD8+ T cells via antigen cross presentation

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**

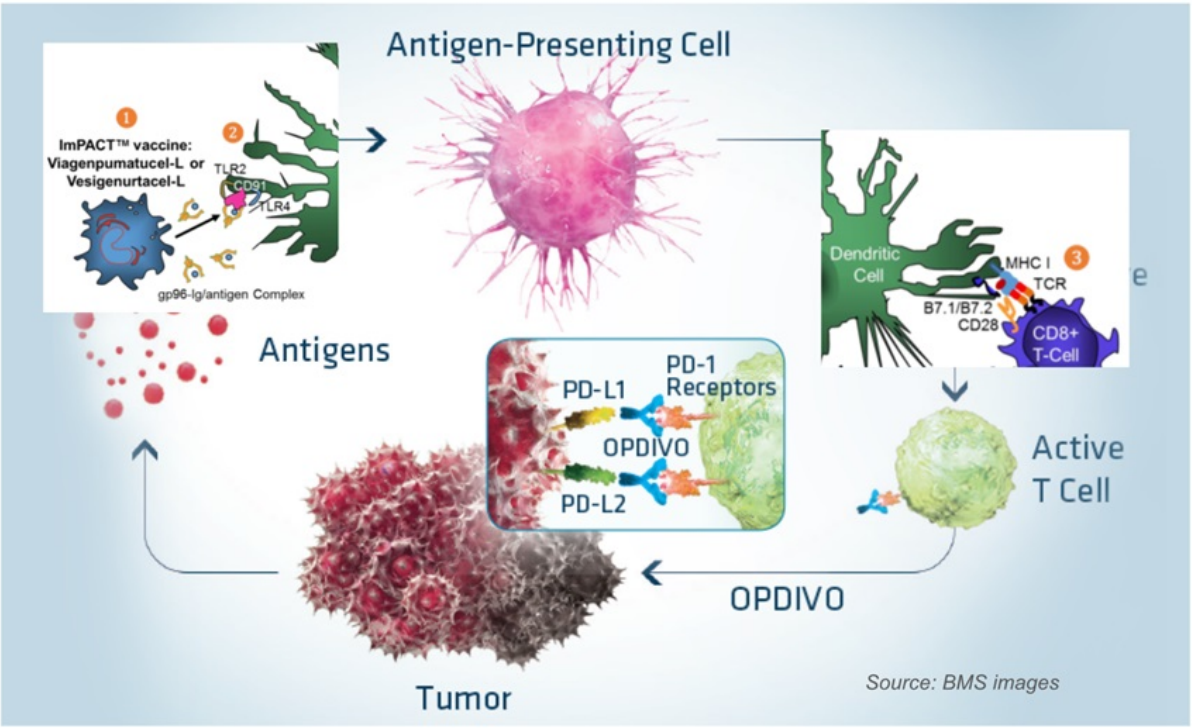
1. **Secretion of gp96-Ig** carrying tumor specific proteins represented on the patients tumor
2. **Activation of APCs** (TLR2/4) and cross-presentation of antigens (CD91)
3. **Specific T-cell receptor** engagement
4. **Clonal Expansion** of Tumor Antigen Specific T cells.



Heat Biologics

ImPACT + Opdivo Combination Therapy

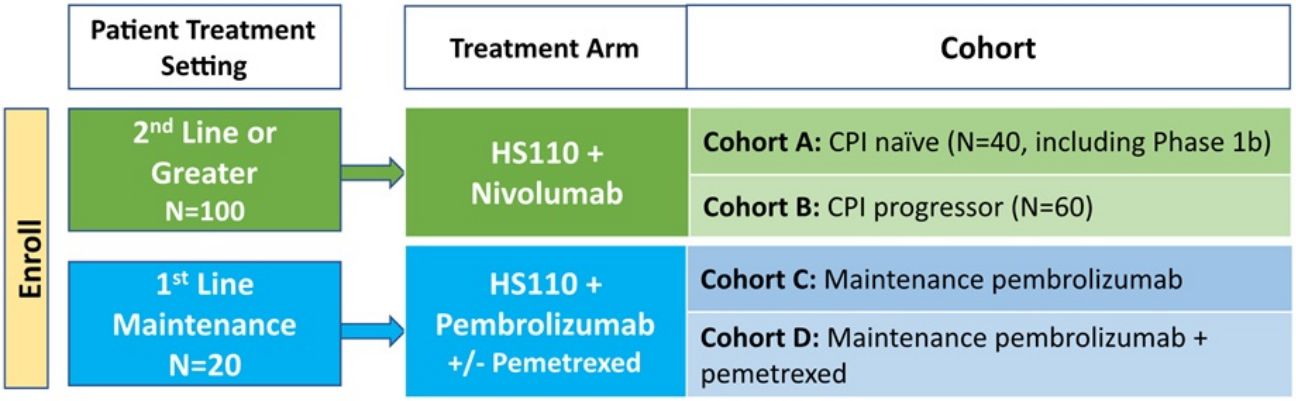
Potential to improve clinical responses and survival, without additional toxicity



Heat Biologics

HS-110 Trial Design

A Phase 1b/2 study of HS-110 in combination with multiple treatment regimens for patients with non-small cell lung cancer (The "DURGA" Trial)



Primary Endpoints

Phase 1b:
Safety

Phase 2:
Cohort A&B: ORR
Cohort C&D: PFS

Secondary Endpoints

OS, PFS, DCR, DOR

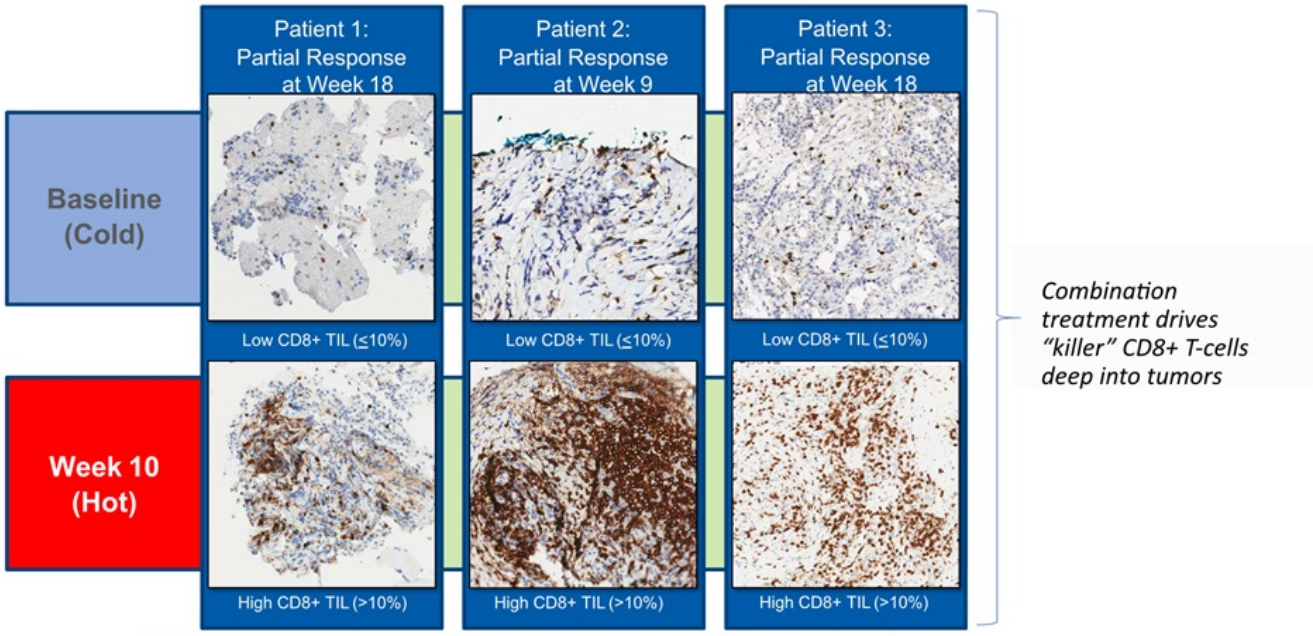
Exploratory Endpoints

Correlation of clinical outcomes to the following factors

- **Baseline CD8+ TILs**
  (Low defined as ≤ 10% stromal CD8+ TILs)
- **PD-L1 expression**
  (Negative defined as < 1% on tumor cells)
- **Peripheral blood tumor mutation burden count**
  (Low defined as < 10 mutation count)
- **ELISPOT cytokine analysis**

Clinical Support for HS-110 + Nivolumab Mechanism of Action

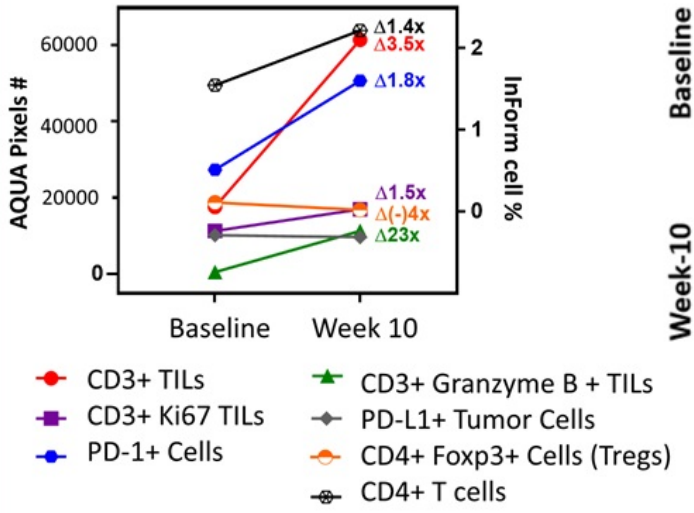
"Turning COLD Tumors HOT"

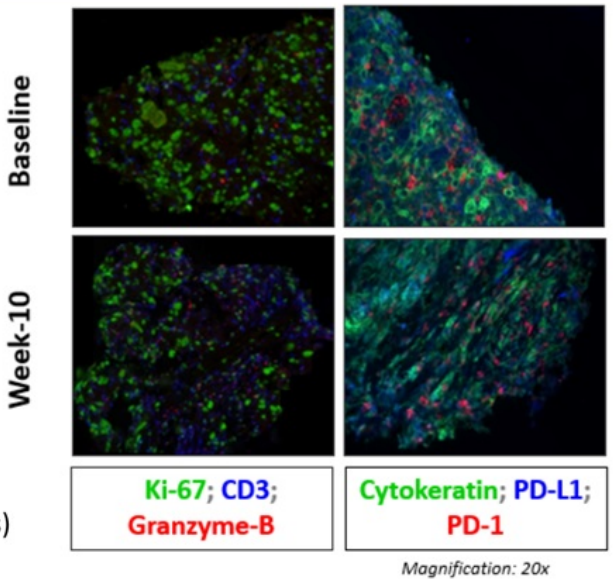


CD8+ TIL Infiltration Associated with Clinical Response

Combination Treatment Substantially Increased Killing Activity in Patient Tumor Microenvironment

RECIST 1.1 Stable Disease for 19+ months





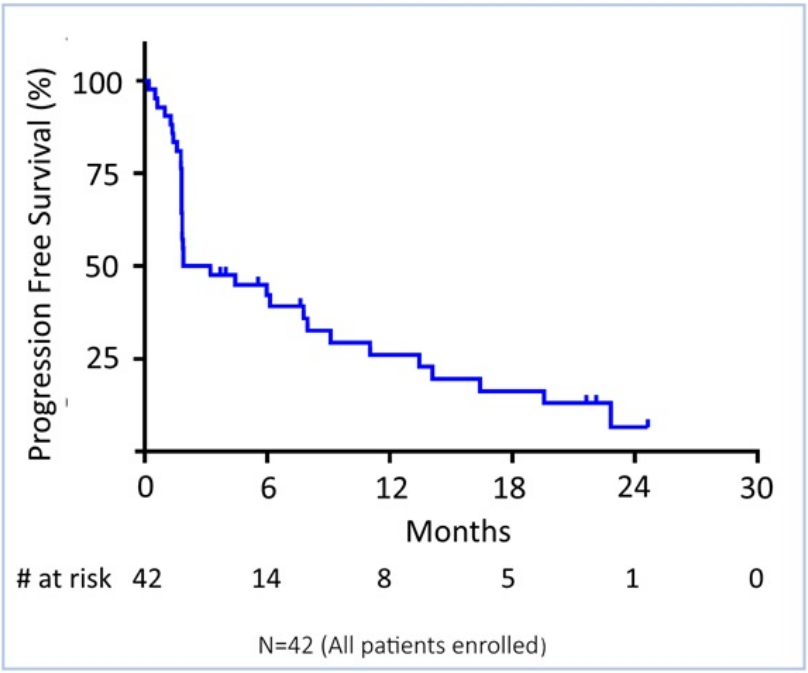
Substantial increase of CD3+ TILs and CD3+ Granzyme B+ TILs for enhanced tumor killing activity

Pathology analysis performed by Yale School of Medicine

Cohort A:

CPI Naïve pts treated by HS-110 + Nivolumab at ≥2L

Progression-Free Survival (PFS)



N=42 (All patients enrolled)

Median PFS
2.6 months
(95% CI: 1.8 - 8 months)

Median PFS of nivolumab alone
2.3 months *
(95% CI: 2.2 – 3.3 months)

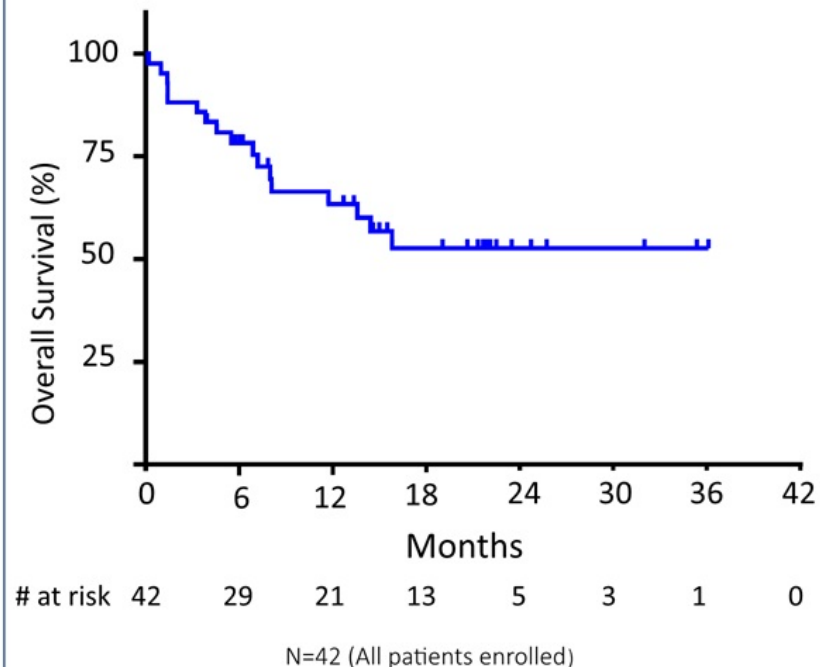
* Borghaei et al. 2015 Nivolumab versus Docetaxel in Advanced Nonsquamous Non–Small-Cell Lung Cancer. *New England Journal of Medicine*

Heat Biologics

Cohort A:

CPI Naïve pts treated by HS-110 + Nivolumab at ≥2L

Overall Survival (OS)



N=42 (All patients enrolled)

Median OS
Not Reached
(95% CI: 8.1 months - NR)

60% of patients still alive with median follow-up time of 14.4 months

Median OS of nivolumab alone 12.2 months*
(95% CI: 9.7 – 15.0 months)

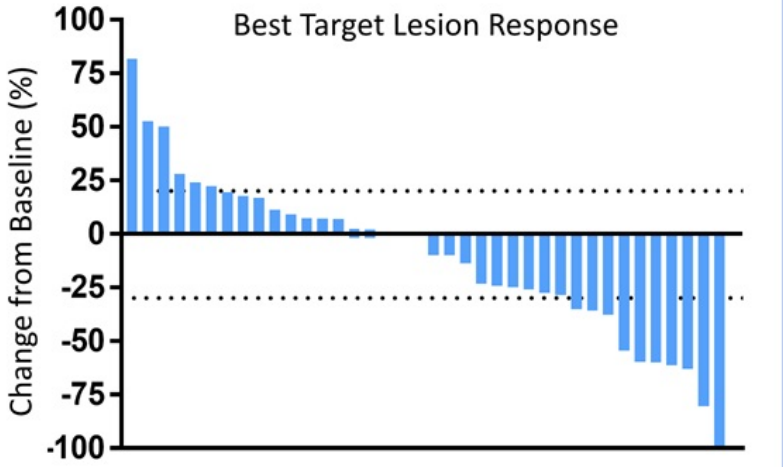
*Borghaei et al. 2015 *NEJM*

Heat Biologics

Cohort A:

CPI Naïve pts treated by HS-110 + Nivolumab at ≥2L

Best Overall Response



Waterfall plot of best target lesion response using percent change from baseline of the SLD (sum of longest diameters) for all patients who received at least 1 post-baseline scan (n=38)

RECIST 1.1 Objective Response Rate = 21.4%
(95% CI: 10.3 - 36.8%)

PR	9 (21%)
SD	12 (29%)
Not evaluable	4 (10%)
DCR	21 (50%)

Nivolumab alone in CPI naïve patients*
ORR = 19% (95% CI: 15% - 24%)
DCR = 44%

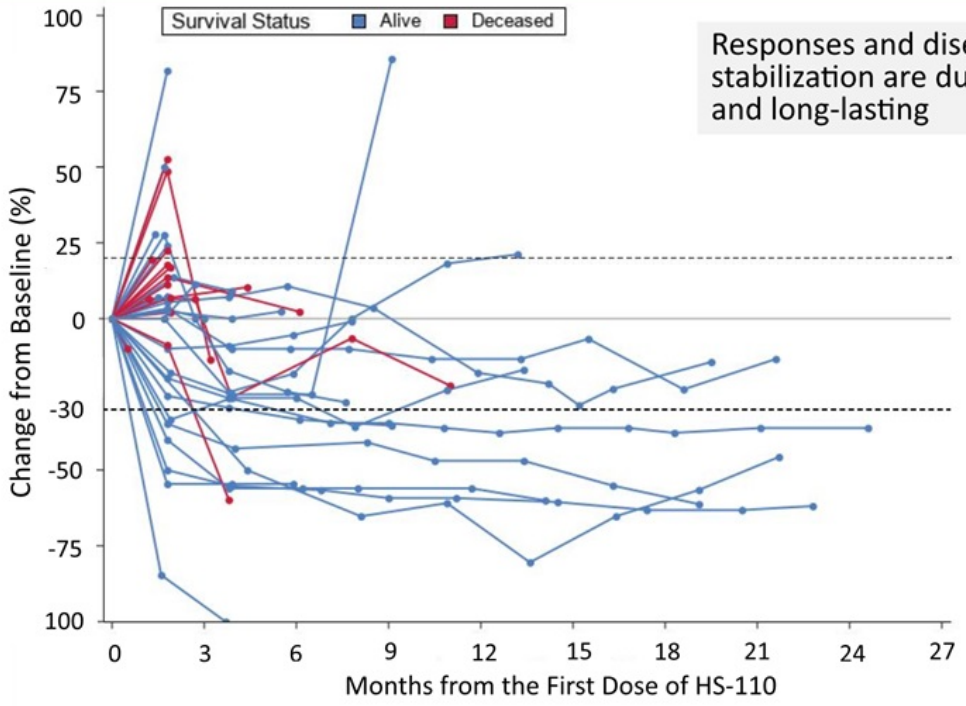
**Borghaei et al 2015 NEJM*

Heat Biologics

Cohort A:

CPI Naïve pts treated by HS-110 + Nivolumab at ≥2L

Duration of Benefit



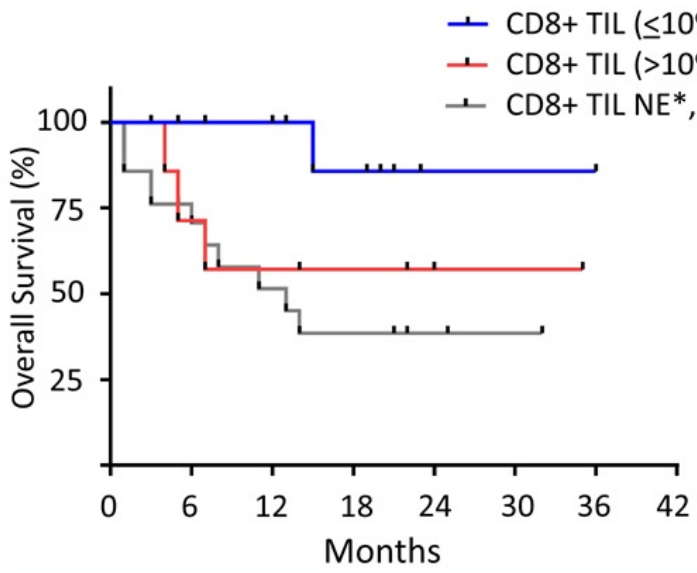
Heat Biologics

Cohort A:

CPI Naïve pts treated by HS-110 + Nivolumab at ≥2L

Improved Survival in "Cold" Tumor Patients

Overall Survival (OS) by Baseline CD8+ TIL



	Low CD8+ TIL (≤ 10%)	High CD8+ TIL (> 10%)
Median OS	NR	NR
	HR 0.39 (95% CI: 0.06 – 2.31)	

*TIL NE = Tumor infiltrating lymphocyte not evaluable

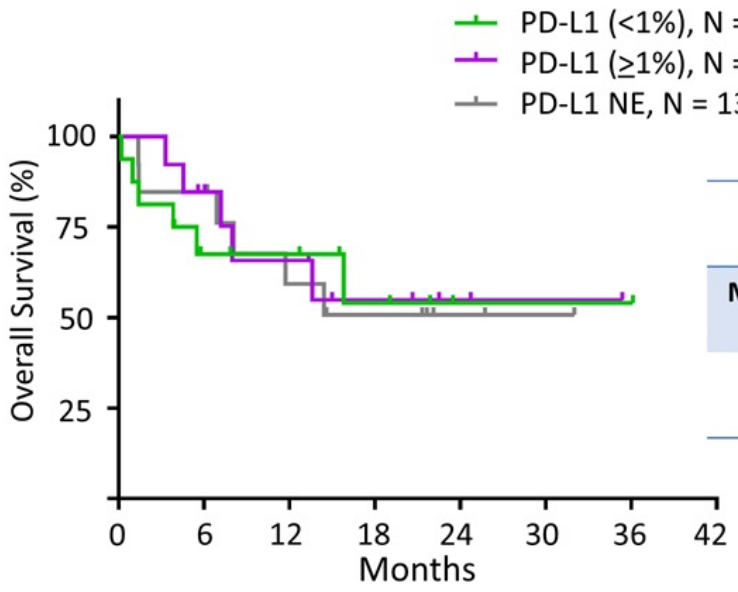
Heat Biologics

Cohort A:

CPI Naïve pts treated by HS-110 + Nivolumab at ≥2L

Benefit Independent of PD-L1 Status

Overall Survival (OS) by Baseline PD-L1 Status



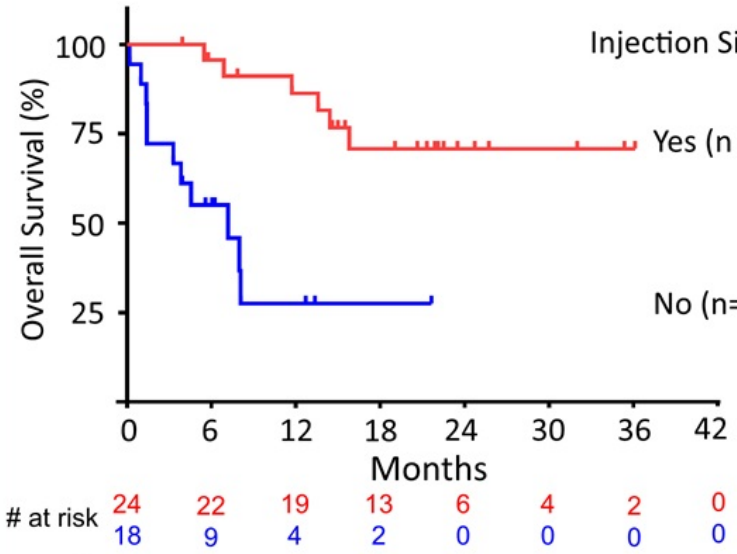
	Negative PD-L1 (< 1%)	Positive PD-L1 (≥ 1%)
Median OS	NR	NR
	HR 0.85 (95% CI: 0.26 – 2.79)	

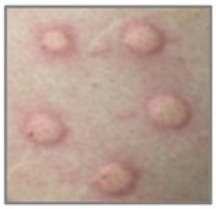
Heat Biologics

Cohort A:

CPI Naïve pts treated by HS-110 + Nivolumab at ≥2L

OS by Injection Site Reaction (ISR)





Typical Injection Site Reaction

mOS: NR vs. 7.2 months
HR: 0.15 (95% CI: 0.05-0.45)
p = 0.0001

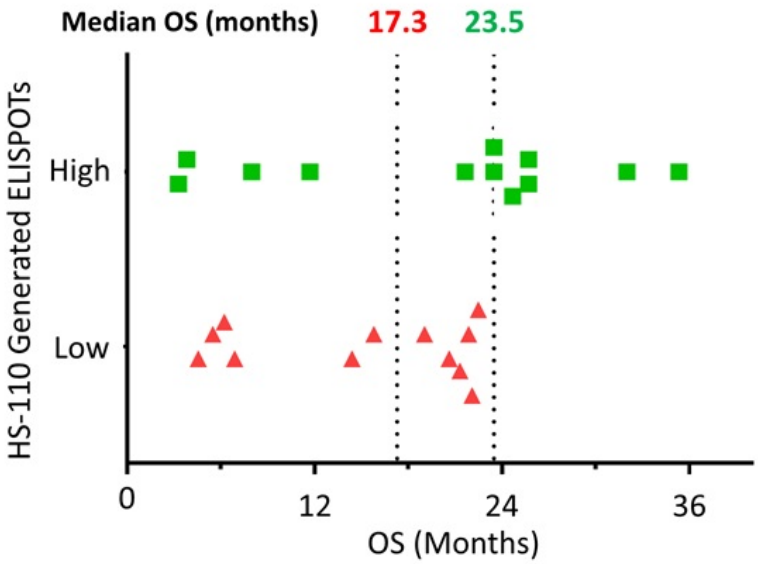
Survival is significantly better in patients who experienced dermal injection site reaction, thus supporting the HS-110 mechanism of action

Heat Biologics

Cohort A:

CPI Naïve pts treated by HS-110 + Nivolumab at ≥2L

Survival Benefit with Increased Immune Activity



Peripheral blood obtained before and during treatment to measure HS-110 derived immune reactivity.

ELISPOTs represent INF-γ secretion from T cells in culture after stimulation with HS-110 lysate.

High = Patients with absolute ELISPOT increases **above** the group median

Low = Patients with absolute ELISPOT increases **below** the group median

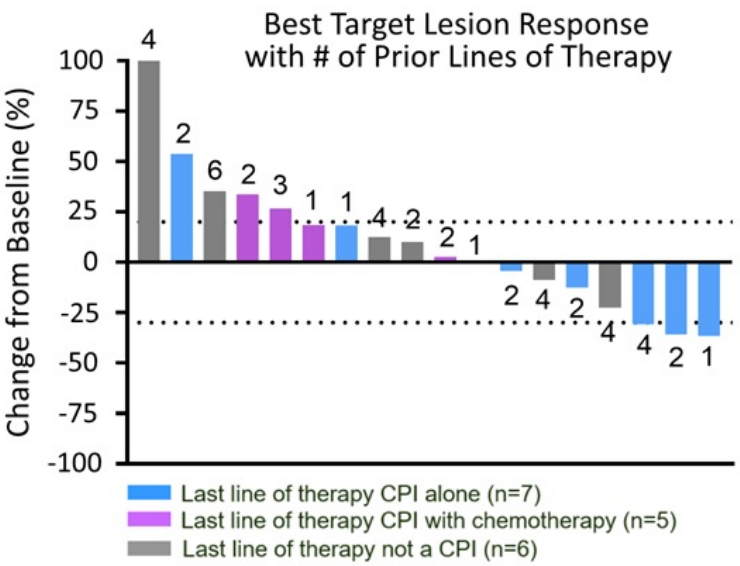
A 6-month improvement of median survival in patients with high HS-110 stimulated immune activity

Heat Biologics

Cohort B:

CPI progressors treated by HS-110 + Nivolumab at ≥2L

Objective Response Rate



RECIST 1.1 ORR = 15%
(95% CI, 3.2 - 37.9%)

PR*	4 (20%)
SD	7 (35%)
Not evaluable	2 (10%)
DCR	**11 (55%)**

* Per Investigator assessment

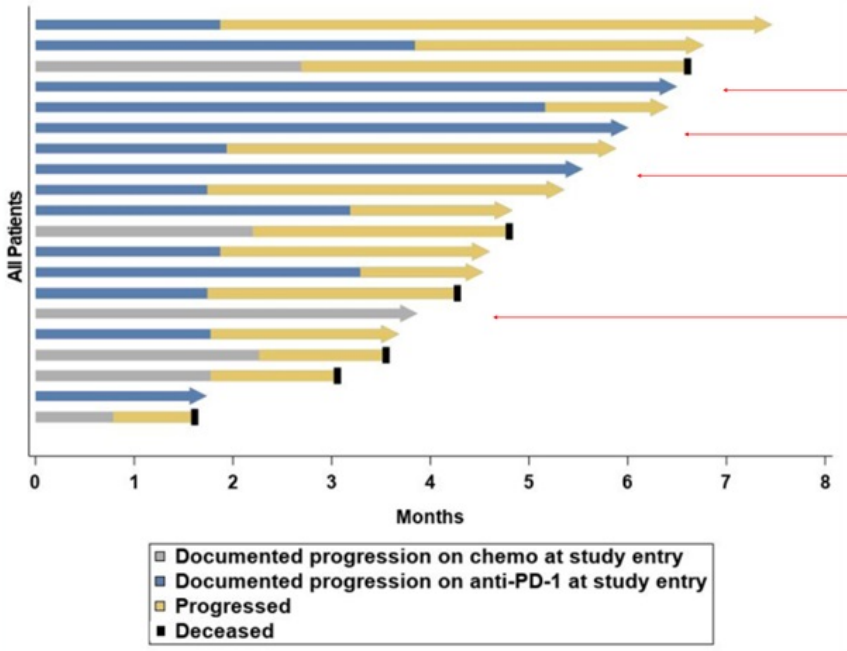
- Stabilization of disease in > 50% of patients
- Response rates suggest that addition of HS-110 can restore responsiveness to CPI therapy
- The 3 RECIST partial responses were in patients who failed CPI immediately preceding study entry

Heat Biologics

Cohort B:

CPI progressors treated by HS-110 + Nivolumab at ≥2L

Duration of Clinical Benefit



4 out of 20 patients have not progressed on therapy

Median Progression-Free Survival (PFS)
2.7 months
(95% CI: 1.8 - 4.0 months)

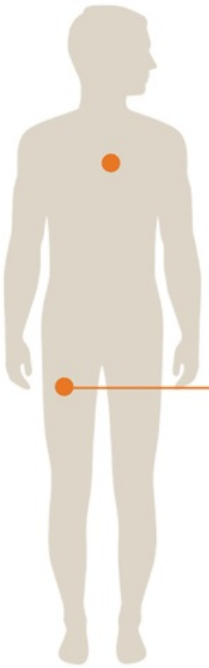
Safety Profile to Date

1,000+ Doses - No Serious Adverse Reactions

Favorable Safety Profile To Date

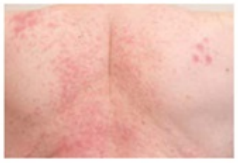
- Over 1,000 doses administered to ~200 patients
- Only one patient ended treatment due to a non-serious adverse reaction*
- No systemic use of steroids required to treat reactions
- No treatment-related serious adverse reactions

No additive toxicities to standard of care



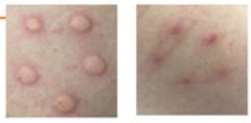
Immune Reaction*

≤ Grade 3 toxicity



Injection Reactions

Week 1 Week 2



*Represents the only patient of ~200 patients dosed who discontinued treatment for a vaccine-related adverse event

Summary of HS-110 Phase 2 Interim Data

- HS-110 in combination with nivolumab is well tolerated
- Preliminary results demonstrate the ability of HS-110 plus nivolumab to induce CD8+ T-cell tumor infiltration in previously "cold" tumors
- In Cohort A, the occurrence of injection site reactions and increased INF-γ ELISPOTs appears to be associated with improved overall survival
- Data in Cohort B suggests that the addition of HS-110 to nivolumab may restore responsiveness after tumor progression on prior checkpoint inhibitors

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

TNFRSF25 represents an emerging target in immuno-oncology

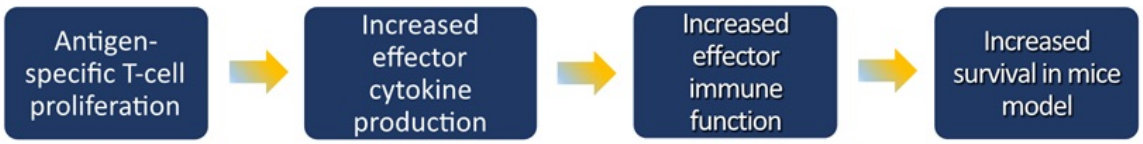
Pre-clinical data of PTX-35 highlights CD8+ T-cell specificity

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)

In mice, TNFRSF25 agonists increases



Compared to agonists OX40, GITR, 4-1BB:

- TNFRSF25 shows superior activity in stimulating memory CD8+ cells in mice
- TNFRSF25 agonism plus *ImPACT* results in improved survival in mouse melanoma models

Corporate Milestones

Corporate Highlights

Nasdaq	Shares Outstanding	Cash & Equiv.	Founded in	Employees	Grant Awarded
HTBX	32.5M	$27.7M	2008	30	$15.2 M

Capitalization Table (as of 12/31/2018)	**Shares**
Common shares outstanding	32.5 M
Warrants	9.0 M
Outstanding stock options	3.1 M
Unvested restricted stock	1.6 M
Fully Diluted Shares Outstanding	46.2 M

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

Clinical Data with Checkpoint Inhibitors (CPI) - Positive interim data from ongoing Phase 2 trial of HS-110 + CPI in non-small cell lung cancer (NSCLC) patients (both CPI naïve and CPI progressors)

Diverse Technology Platforms - Multiple complementary platform technologies

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

Appendix

Heat Biologics

Cohort A & B: Patient Characteristics

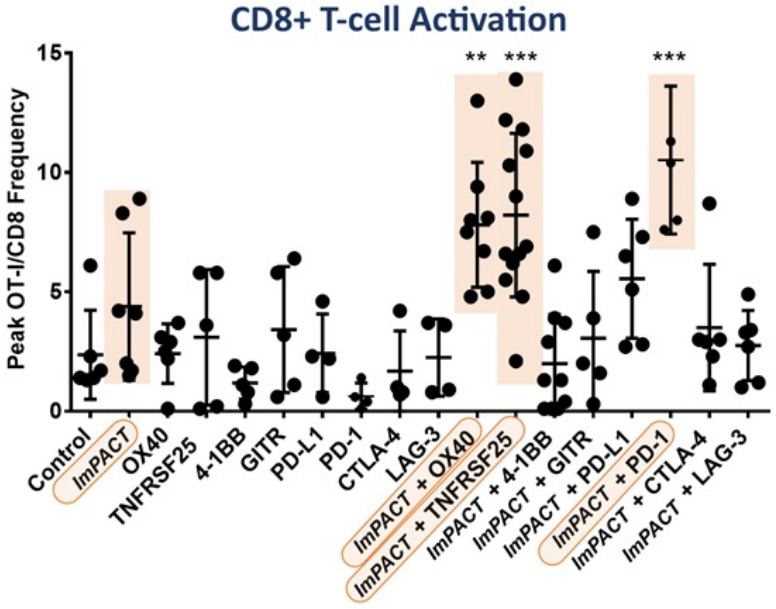
Stage III or IV advanced NSCLC

		Cohort A (N = 42)	Cohort B (N = 20)
Median age (range)		64 (37-87)	65 (56-84)
Female gender		22 (52%)	14 (70%)
Caucasian		38 (90%)	15 (75%)
ECOG PS 1		26 (62%)	10 (50%)
Histology	Adeno	39 (93%)	17 (85%)
	Squamous	3 (7%)	3 (15%)
Smoking Status	Current/past	37 (88%)	17 (85%)
	Never	5 (12%)	3 (15%)

		Cohort A (N = 42)	Cohort B (N = 20)
EGFR or ALK positive		9 (22%)	2 (10%)
Prior lines	1	27 (64%)	3 (15%)
	2 or more	13 (30%)	16 (80%)
	Unavailable	2 (5%)	1 (5%)
PD-L1	< 1%	16 (38%)	7 (35%)
	≥ 1%	13 (31%)	8 (40%)
	Unevaluable	13 (31%)	5 (25%)
CD8+ TIL	≤ 10%	12 (29%)	7 (35%)
	> 10%	8 (19%)	6 (30%)
	Unevaluable	22 (52%)	7 (35%)

Preclinical Data of CD8+ T cell Activation

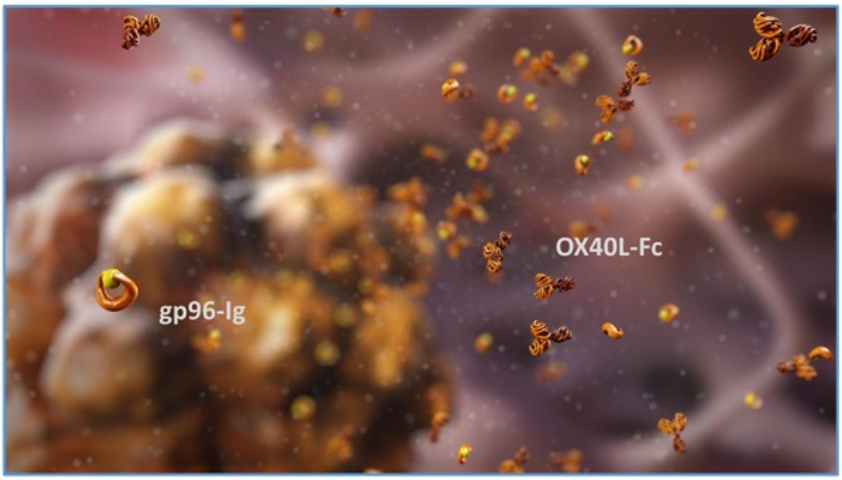
ImPACT® alone and in combination with co-stimulator agonists: OX40, TNFRSF25, PD-1



- Higher T-cell responses observed in mice treated with *ImPACT* alone
- *ImPACT®* boosted CD8+ 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

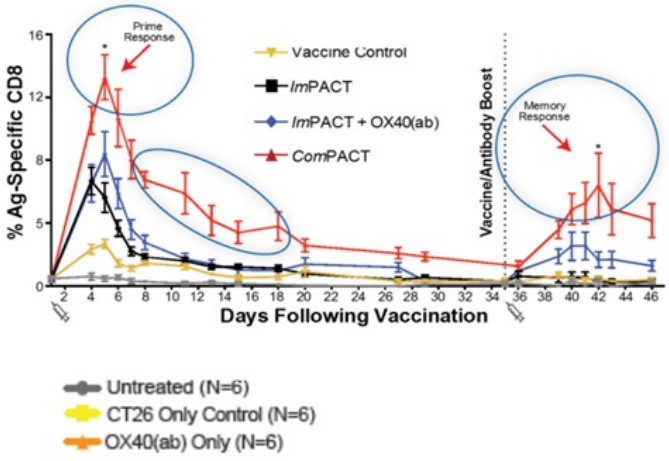


The first potential dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product – combination therapy without additive costs

ComPACT™ Outperforms OX40

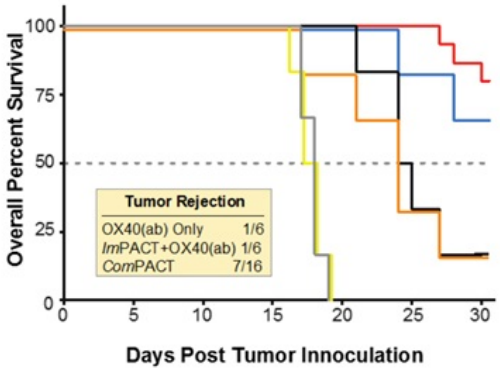
Monoclonal Antibodies in Pre-clinical Models

Superior primary and memory T-cell response in mouse model



Untreated (N=6)
CT26 Only Control (N=6)
OX40(ab) Only (N=6)

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



*Im*PACT (N=6)
*Im*PACT + OX40(ab) (N=6)
*Com*PACT (N=6)

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

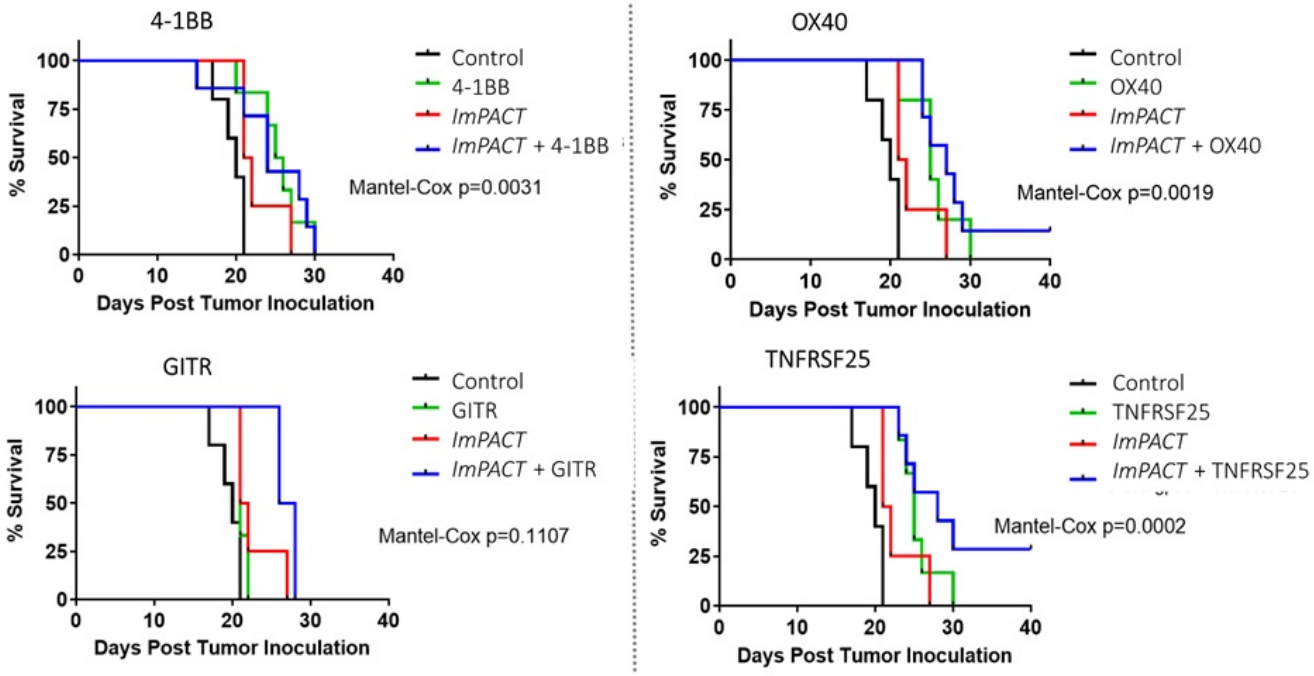
TNFRSF25 - An Emerging Target for T-cell Co-stimulation

Target	Companies	Co-stimulator Combinations
4-1BB	Pfizer, ISA Pharma, Gilead, Bristol Myers, Inhibrx, Immatics, Pieris, NCI	**Phase 1/2** Combinations: Chemotherapy, epigenetic modulator, CD20 mAb, HPV vaccine, CART, PD-L1, BTK, Herceptin, modified CD8+ T cells, IL-2, CSF1R, LAG-3, bispecific w/ HER-2, two co-stimulators (w/ OX40)
OX40	MedImmune, GSK, Incyte, Genentech, Pfizer, AbbVie, Bristol Myers, Alligator Bio	**Phase 1/2** OX-40 prior to surgery. Other combinations: PD-1, PD-L1, CTLA4, axitinib, 41BB, smoothened inhibitor Anti-CD33, azacitidine, TLRs, bi-specifics of OX40 and CTLA-4
GITR	Novartis, Incyte-Agenus, MedImmune, Leap Therapeutics, BMS, OncoMed	**Phase 1** Combinations: PD-1, Fc disabled co-stimulation, hexameric GITR ligand, IDO inhibitor, CTLA-4, GITR ligand-fusion
CD27	Celldex-BMS, Merck-Aduro	**Phase 1/2** Combinations: PD-1/L-1, sunitinib, CD20, melanoma vaccine, TL3 agonist
ICOS	Celgene-Jounce, GSK	**Phase 1/2** Combinations: PD-1, CTLA4, docetaxel
TNFRSF25	Heat (under Pelican)	Filing IND in Q2 2019 in advanced solid tumors. Combination studies being planned

- TNFRSF25 is a potential best-in-class T cell co-stimulator due to its **preferential specificity to 'memory' CD8+ T cells**
- **Pelican is the only company** with a disclosed program targeting TNFRSF25

TNFRSF25 agonist + *ImPACT* Significantly Increases Survival in Mice

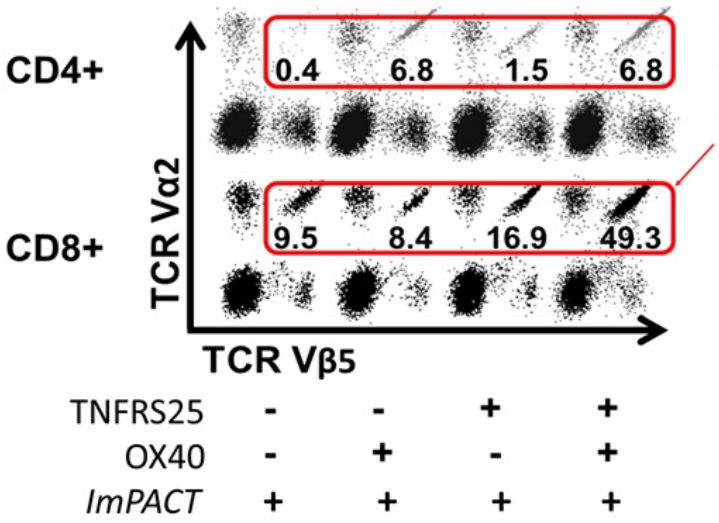
Nine-day B16-F10 melanoma model



Schreiber T. et al. SITC 2014

Preferential CD8+ T-cell Induction with TNFRSF25 in Mice

Pre-clinical studies with murine agonist antibody shows
TNFRSF25 preferentially 'boosts' CD8+ T-cells, whereas OX40 is preferential to CD4+ T-cells



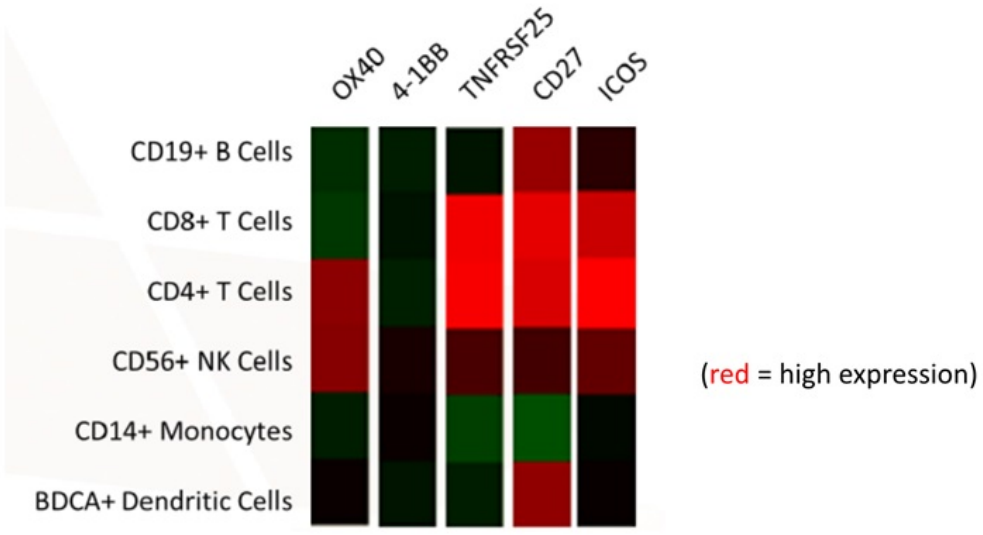
% Antigen Specific Memory CD8+ T-cells

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

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

TNFRSF25 is preferentially expressed on CD8+ T-cells

compared to other T-cell co-stimulators



Genomics Institute of the Novartis Research Foundation Su *et al*. PNAS 2004:**101**(16);6062-7

Heat Biologics

Management and Advisors

Management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Founder & CEO


Jeff Hutchins, Ph.D.
CSO/COO


George Peoples, MD
Chief Medical Advisor


Ann Rosar
VP of Finance


Janice McCourt
VP of Business Devt.


Lori McDermott
VP of Clinical Dev.


Gary Vinson
VP of Manufacturing

Scientific Advisors

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Robert Negrin, MD
Stanford University

Anthony Tolcher, MD
Next Oncology

Roger Cohen, MD
University of Pennsylvania

Llew Keltner, MD, Ph.D.
Epistat

Gary Acton, MD
Advisor

Board of Directors

Jeff Wolf
Founder, Chairman and CEO

John Prendergast, Ph.D.
Lead Independent Director

John Monahan, Ph.D.
Director

Edward Smith
Director