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): **May 7, 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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0002 par value per share	HTBX	The Nasdaq Capital Market

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. Corporate 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: May 7, 2019

HEAT BIOLOGICS, INC.

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


Heat Biologics
Heat Biologics
NASDAQ: HTBX
CORPORATE PRESENTATION
May 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/A for the year ended December 31, 2018, our quarterly reports on Form 10-Q for the subsequent quarters and our other subsequent filings with the Securities and Exchange Commission (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.

Snapshot of Heat Biologics (Nasdaq: HTBX)

US-based biopharmaceutical company developing a suite of immunotherapy products designed to

"Turn Cold Tumors Hot"

HS-110, an "off the shelf" cell-based immunotherapy product that has the potential to improve PD(L)-1 based therapy

- Planning for registrational trial
- Ongoing Phase 2 program demonstrates signals of efficacy in two treatment settings
- Broad market potential in multiple oncology indications
- Fully allogeneic product with low COGs

Promising pipeline based on T-cell activation and co-stimulation

- Two additional candidates with targeted IND filing in 2019
- Product pipeline offers additive clinical benefit when combined with anti-PD-(L)1 and other immunotherapies

Experienced management team with proven track record advancing oncology drugs to the market

Seeking commercial partners for HS-110 to realize platform potential

Heat Biologics

Product Pipeline

Product	MOA (Modality)	Indication	Preclinical	Phase 1	Phase 2	Phase 3
HS-110	gp96 (Cell Therapy)	NSCLC				
HS-130	gp96 + OX40L (Cell Therapy)	Multiple Solid Tumor				
PTX-35	TNFRSF25 (mAb)	Multiple Solid Tumor				

HS-110 Overview

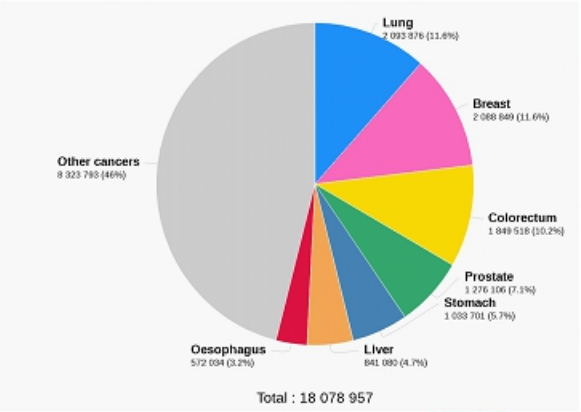
- **HS-110 is a Phase 2 cell-based immunotherapy administered in combination with PD-(L)1 therapies to improve clinical outcomes for NSCLC patients**
  - Allogeneic cells with engineered gp96 to present 70+ different cancer testis antigens
  - Selectively activate CD8+ "killer" T cells
  - Enable infiltration of CD8+ T cells into the tumor microenvironment
- **PD-(L)1 is approved for multiple cancers but clinical benefit is not observed in majority of biomarker-unselected patients**
  - In unselected NSCLC patients treated in second line or greater, the response rate to anti-PD(L)1 antibodies is 13.6% to 23% ‡

The combination of HS-110 and PD-(L)1 therapy may benefit patients that have progressed on prior PD-(L)1 therapy

‡ *Shukuya & Carbone 2016. Journal of Thoracic Oncology, Vol.11 No.7: 976 - 988*

Top 7 Cancers Worldwide by Incidence

Estimated Number of New Cases in 2018 Worldwide



Total : 18 078 957

Cancer	Cases	
	Number	Percentage
Lung	2 093 876	11.6%
Breast	2 088 849	11.6%
Colorectum	1 849 518	10.2%
Prostate	1 276 106	7.1%
Stomach	1 033 701	5.7%
Liver	841 080	4.7%
Esophagus	572 034	3.2%
Other cancers	8 323 793	46%

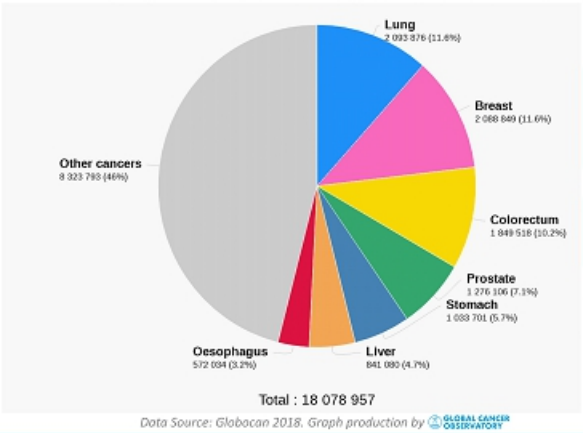
Data Source: Globocan 2018. Graph production by GLOBAL CANCER OBSERVATORY

International Agency for Research on Cancer
World Health Organization

Heat Biologics

PD(L)-1 Therapy is Approved for Multiple Cancers

Estimated Number of New Cases in 2018 Worldwide



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PD(L)-1 approved indications in US*

* Including microsatellite instability-high cancer

Data Source: Globocan 2018. Graph production by GLOBAL CANCER OBSERVATORY

International Agency for Research on Cancer
World Health Organization

Heat Biologics

Combination of HS-110 and PD(L)-1 therapy

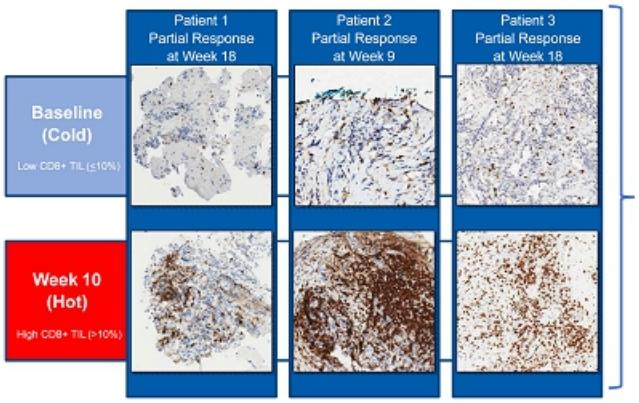
- HS-110 is designed to overcome mechanisms of immune evasion, thereby having the potential to enable effective treatment with PD(L)-1
  - Target to be effective in patients that generally do not benefit from PD(L)-1 therapy

*Pie chart for illustrative purposes and not drawn to scale

Heat Biologics

Clinical Support for HS-110 + Nivolumab MOA

"Turning COLD Tumors HOT"



Combination treatment drives "killer" CD8+ T-cells deep into tumors

CD8+ TIL Infiltration Associated with Clinical Response

Data from Phase 1b/2 trial in advanced NSCLC patients treated by HS-110 + Nivolumab at ≥2L

Heat Biologics

HS-110 Clinical Data

A Phase 1b/2 Study of HS-110 in Combination with Multiple Treatment Regimens in Patients with NSCLC

This is a non-randomized, open-label study that assesses HS-110 in combination with nivolumab or pembrolizumab in four different patient populations with advanced NSCLC

HS-110 + Nivolumab

A. 2+ line Checkpoint Inhibitor (CPI) naïve patients

B. 2+ line patients that progressed following CPI treatment

HS-110 + Pembrolizumab ± Pemetrexed

C. 1st line patients achieving SD/PR prior to pembrolizumab maintenance therapy

D. 1st line patients achieving SD/PR prior to pembrolizumab + pemetrexed maintenance therapy

Primary Endpoints

- Cohort A & B: **ORR**
- Cohort C & D: **PFS**

Secondary Endpoints

- **OS, PFS, DCR, DOR**

Exploratory Endpoints

- **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 mutations/ Mb)
- **ELISPOT cytokine analysis**

Cohort A: PD-(L)1 naïve patients

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

Stage III or IV advanced NSCLC patients

From Heat Phase 2 Trial Interim Results

	HS-110 + Nivolumab	
	ITT (N = 42)	Per Protocol (N = 36)
ORR	21.4%	22.2%
DCR	50%	53%
PFS	2.6 months	4.6 months
Median OS	**Not Reached** 60% of pts still alive with median follow-up time of 14.4 months	**Not Reached** 67% of pts still alive with median follow-up time of 14.4 months

As of last data cut-off in January, 2019

From BMS Checkmate-057 trial

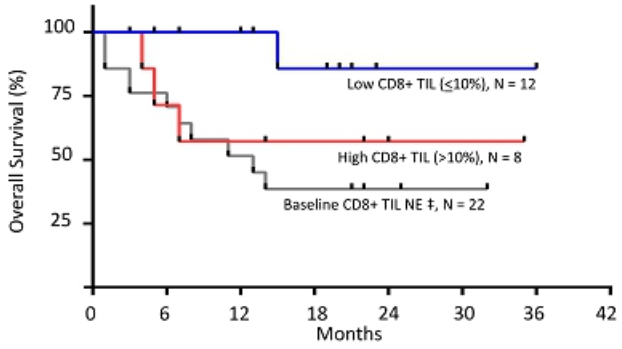
Nivolumab*
ITT (N = 292)
19.0%
44%
2.3 months
12.2 months

*Borghaei et al. 2015 *New England Journal of Medicine. 373:1627-39*

*Borghaei et al. 2015 *New England Journal of Medicine. 373:1627-39*

Cohort A:
CPI naïve pts treated by HS-110 + Nivolumab at ≥2L

Improved Survival in "Cold" Tumor Patients
In contrast to current literature*



Survival benefit observed in patients with low CD8+ TIL at baseline
as compared to high CD8+ TIL at baseline
HR = 0.39 (95% CI: 0.06 – 2.31)

As of last data cut-off in January, 2019

*Gibney et al. 2016 *Lancet Oncology*. December 17(12): e542–e551

‡ Tumor infiltration lymphocyte not evaluable at baseline

Heat Biologics

Cohort B: PD(L)-1 progressors

Advanced NSCLC CPI Progressors Treated by HS-110 + Nivolumab at ≥2L

From Heat Phase 2 Trial Interim Results

	HS-110 + Nivolumab
	ITT (N = 20)
ORR	15.0%* ** Investigator-assessed ORR = 20%*
DCR	55%
PFS	2.7 months
Median OS	Not Reached Median follow-up time = 43 days

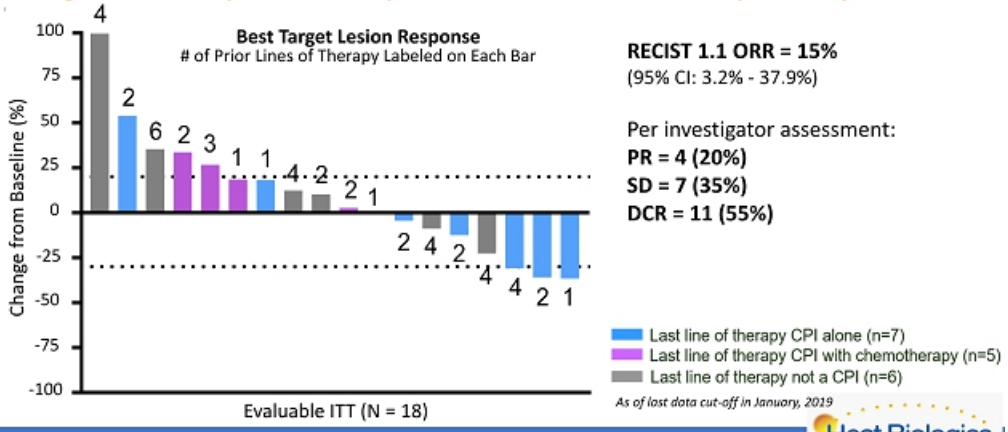
As of last data cut-off in January, 2019

- Stage III or IV advanced NSCLC patients
- Patients are heavily pretreated
  - 80% with 2 or more prior lines of therapy

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

Addition of HS-110 May Restore Responsiveness in PD(L)-1 Progressors

Signal of efficacy observed in patients that have failed multiple therapies



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

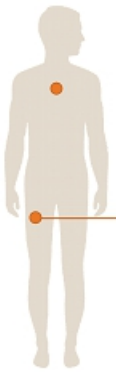
Per investigator assessment:
PR = 4 (20%)
SD = 7 (35%)
DCR = 11 (55%)

Last line of therapy CPI alone (n=7)
Last line of therapy CPI with chemotherapy (n=5)
Last line of therapy not a CPI (n=6)

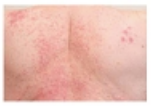
As of last data cut-off in January, 2019

Heat Biologics

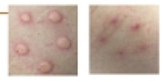
Safety Profile to Date



Immune Reaction*
≤ Grade 3 toxicity



Injection Reactions
Week 1 Week 2



*Represents the only patient of 120+ patients dosed who discontinued treatment for a vaccine-related adverse event

As of last data cut-off in January, 2019

1,000+ Doses - No Serious Adverse Reactions

Favorable Safety Profile To Date

- Over 1,000 doses administered to 120+ patients
- No increase in immune-related adverse events (irAE)
- No systemic use of steroids required to treat reactions
- No suspected unexpected serious adverse reactions (SUSARs)

No additive toxicities to standard of care

Heat Biologics

Product Pipeline

Product	MOA (Modality)	Indication	Preclinical	Phase 1	Phase 2	Phase 3
HS-110	gp96 (Cell Therapy)	NSCLC				
HS-130	gp96 + OX40L (Cell Therapy)	Multiple Solid Tumor				
PTX-35	TNFRSF25 (mAb)	Multiple Solid Tumor				

HS-130 Overview

- **HS-130 is a "off-the-shelf" cell-based immunotherapy product**
  - Leverage HS-110 clinical experience and manufacturing know-how
  - Addition of OX40L to extend and expand T cell memory
  - IND filing expected in 2019
- **Mechanism of Action offers broad market potential**
- **Heat Biologics has worldwide rights**
- **Partnership opportunities available**

Product Pipeline

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HS-110	gp96 (Cell Therapy)	NSCLC				
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PTX-35	TNFRSF25 (mAb)	Multiple Solid Tumor				

PTX-35 Overview

- **Potential first-in-class T cell co-stimulator targeting TNFRSF25, with preferential specificity to generate "memory" CD8+ T cells**
  - IND filing expected in 2019
- **Broad market potential**
  - Efficacy demonstrated in multiple preclinical *in vivo* colon, lung and breast cancer models
- **Synergistic combination with immunotherapies including HS-110 and CPIs**
- **Awarded a $15.2M grant to fund 70 pt. clinical trial**
- **Heat Biologics has worldwide rights**
- **Partnership opportunities available**

2019 Corporate Milestones

Heat Biologics

Heat Biologics' Value Proposition

Unique platform based on harnessing natural innate immunity with transformative capacity of *"Turning Cold Tumors Hot"* and restoring responsiveness to patients failing CPI therapy

HS-110, an "off the shelf" cell-based immunotherapy product that has the potential to improve PD(L)-1 based therapy

- Planning for registrational trial
- Ongoing Phase 2 trials demonstrate signals of efficacy in two treatment settings
- Broad market potential in multiple oncology indications
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Promising pipeline based on T-cell activation and co-stimulation

- Two additional candidates with targeted IND filing in 2019
- Product pipeline offers additive clinical benefit when combined with anti-PD-(L)1 and other immunotherapies

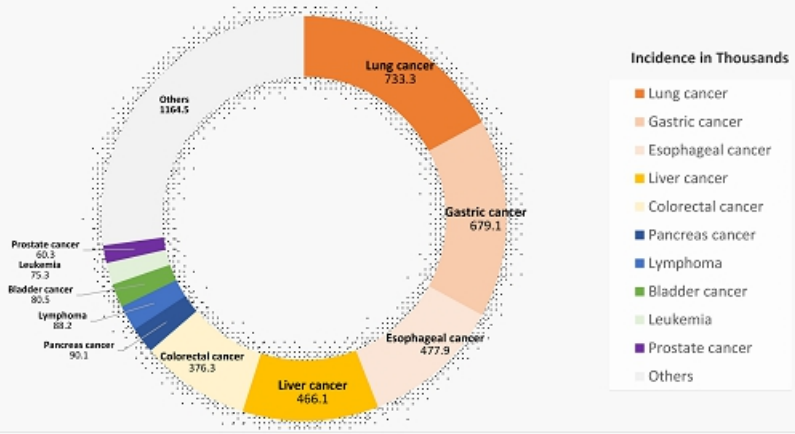
Experienced management team with proven track record in advancing multiple cancer drugs to the market

Seeking commercial partners for HS-110 and HS-130 to realize platform potential

Heat Biologics


Heat Biologics
Heat Biologics
NASDAQ: HTBX
APPENDIX

Top 10 Cancers in China by Incidence



Chen et al. 2016 CA Cancer J Clin 66: 115-132

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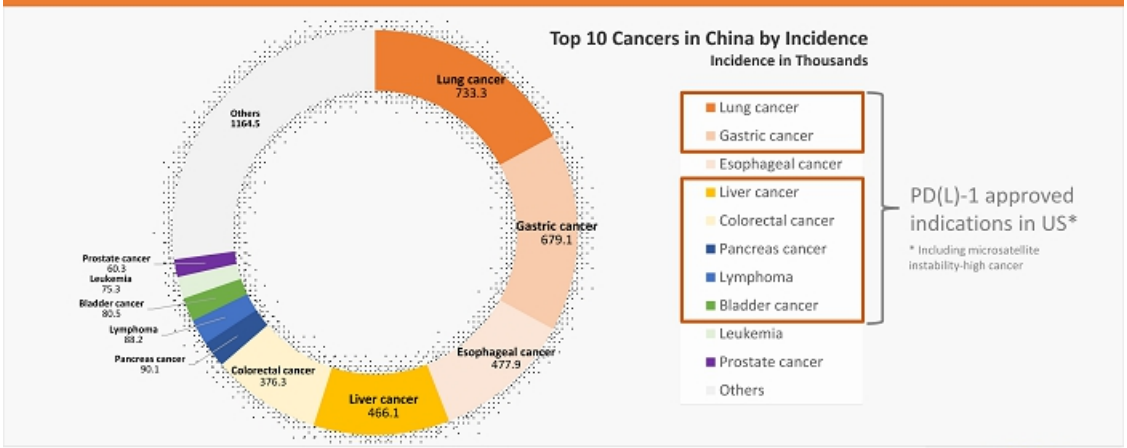
PD(L)-1 Therapy is Approved for Multiple Cancers



Chen et al. 2016 CA Cancer J Clin 66: 115-132

Heat Biologics

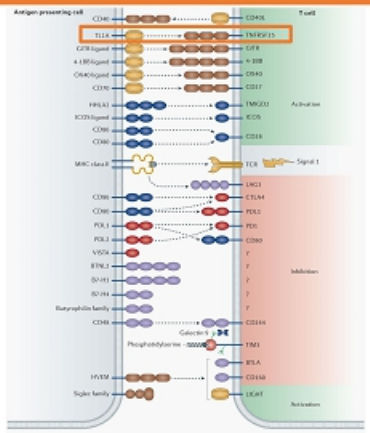
TNFRSF25 as a Novel I/O Combination Target

- TNFRSF25 is one of the most recently discovered T cell costimulator, and is a rapidly emerging target

- Pelican is the only company developing TNFRSF25 agonist antibodies for I/O

"Although TNFRSF25 is chromosomally localized with 4-1BB, OX40, GITR and CD27, sequence analysis suggests that TNFRSF25 is relatively divergent or perhaps ancestral...
Thus we might expect that therapeutics directed against this pathway will have unique activity."

Comment from Gordon Freeman et al

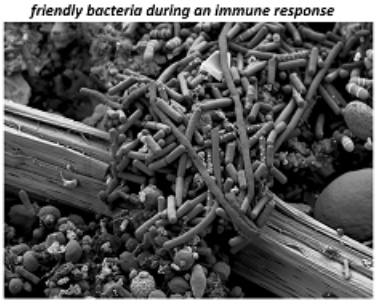


Mahoney K. *et al.* Nat Rev Drug Discov. 2015

TNFRSF25: Why So Complicated?

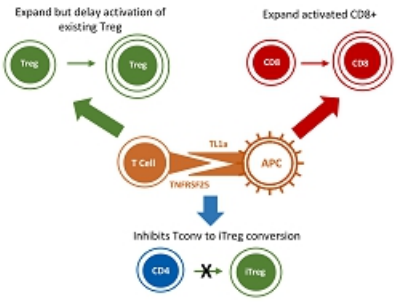
TNFRSF25's evolutionary origin

Potentially a mechanism that preserves needed tissue and friendly bacteria during an immune response



Example: gut invasion occurs in the context of friendly microbiome bacteria. How does the body protect what is needed while weeding out invaders?

One molecule – three types of T-cells



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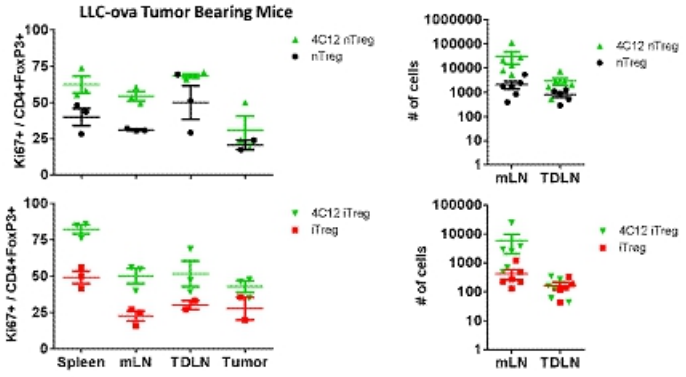
TNFRSF25 Causes No Intra-tumoral T-reg Proliferation in a Lung-tumor Model

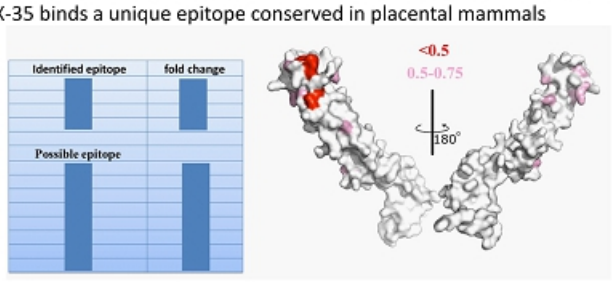


George Fromm et al 2014 Heat Biologics Internal Data

Heat Biologics

Development of Agonist Antibody: PTX-35

- The lead mAb, PTX-35, was affinity-matured and selected based on functional activation of TNFRSF25 across species
- The functional cross-reactivity of PTX-35 was further validated by demonstrating that PTX-35 binds a unique epitope conserved in placental mammals



- Humanized and affinity matured PTX-35 is now in IND enabling development
- IND filing slated for 2Q2019

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