

---

---

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 15, 2016**

**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))
- 
- 
- 
-

**Item 7.01. – Regulation FD Disclosure**

Heat Biologics, Inc. (the “Company”) will be making several investor presentations over the next few weeks. In connection with the presentations, the Company intends to discuss the updated slide presentation which reflects the current focus of our clinical programs furnished 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 information included in this Item 7.01 and in Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing. 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.

The following exhibit is being filed as part of this Report.

<u>Exhibit Number</u>	<u>Description</u>
<a href="#"><u>99.1</u></a>	Presentation materials to be provided at Heat Biologics, Inc.’s presentations

---

**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 15, 2016

HEAT BIOLOGICS, INC.

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



NASDAQ:HTBX

March 2016

## Forward Looking Statements

This presentation includes statements that are, or may be deemed, "forward-looking statements." 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 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, 2015 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.



## Platform technologies designed to activate CD8+ T cells against multiple tumor antigens

### »» **Clinical evidence of mechanism of action**

*Increased CD8+ T cells in tumors associated with clinical response*

»» *Favorable safety profile to-date*

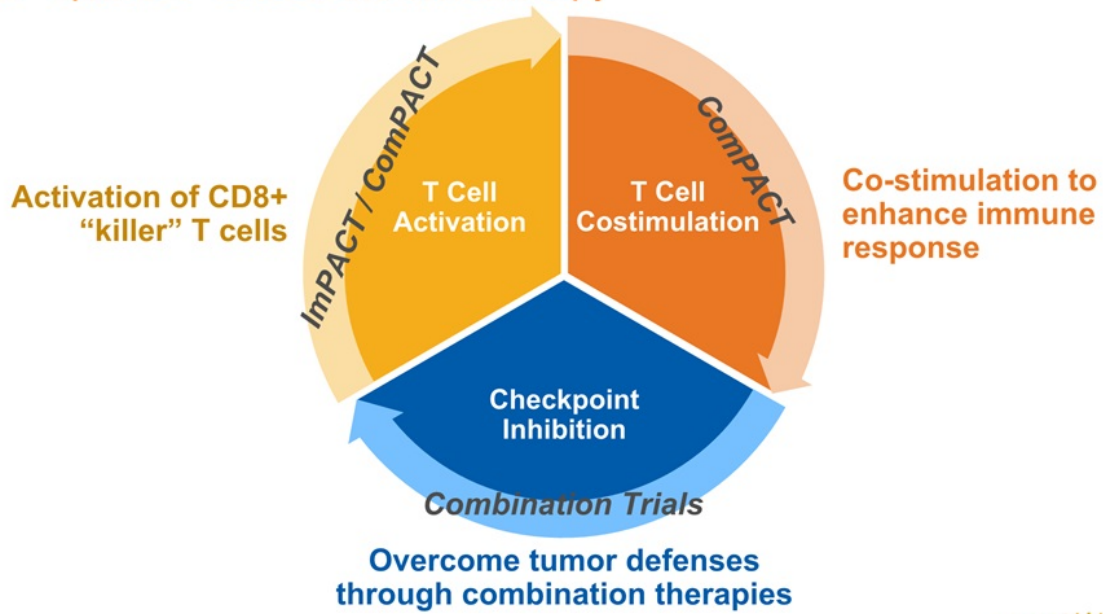
Developing first new immunotherapy  
in non-muscle invasive bladder  
cancer (NMIBC)

Conducting first vaccine + PD-1  
checkpoint inhibitor combo trial in non-  
small cell lung cancer (NSCLC)

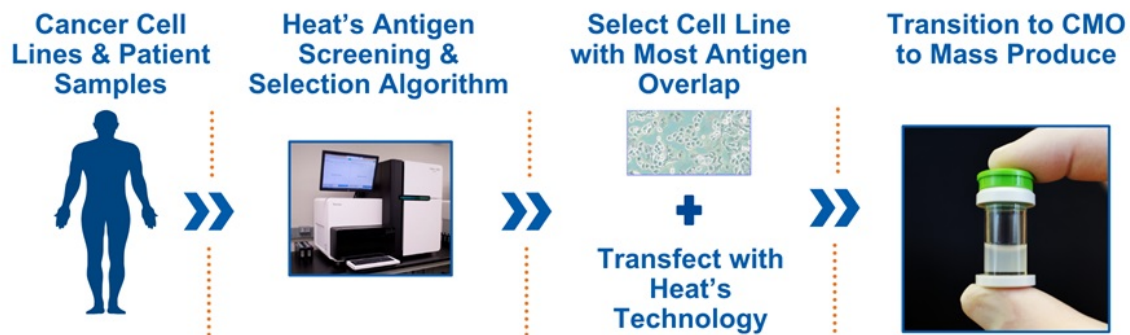
Immuno-oncology company developing novel therapies  
to activate a patient's immune system against cancer

## Vision and Strategy

Addressing Three Distinct But Synergistic Mechanisms of Action to Optimize Cancer Immunotherapy



# Heat's Product Development

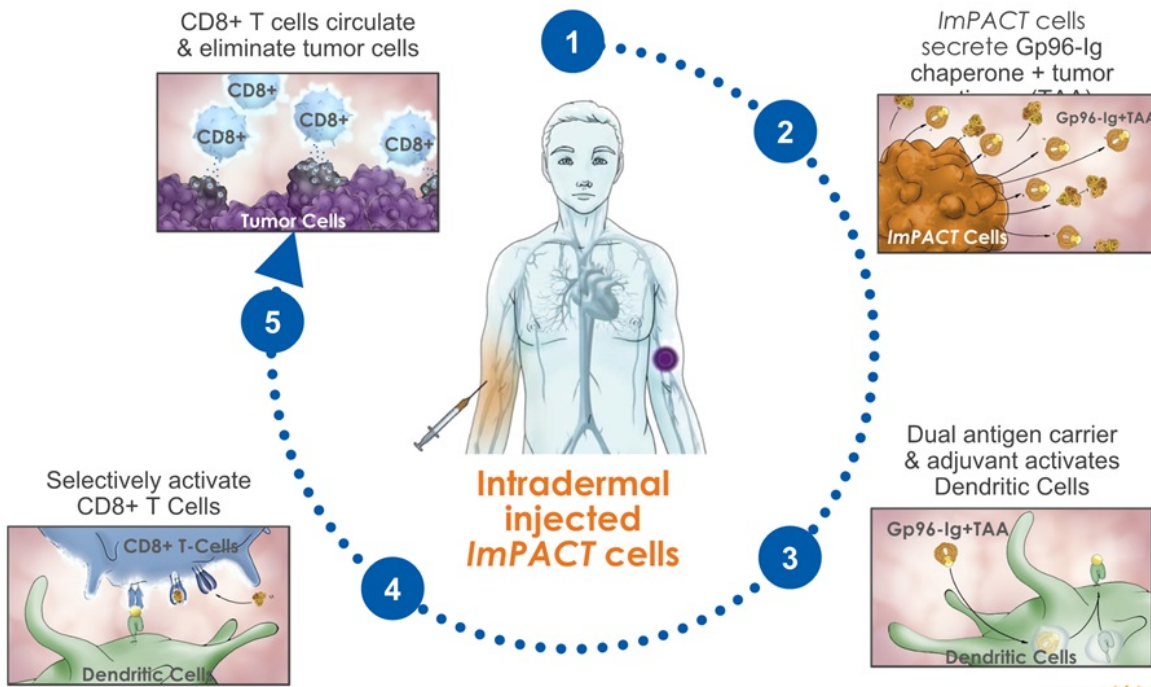


## Platform Technology Highlights

- Applies to multiple cancers
- Designed to activate killer T cells
- Targets multiple tumor antigens
- Enables scalable, low cost manufacturing relative to autologous cell therapies



# ImPACT Platform Technology



# Pipeline

## ImPACT

	Product	Combination	Indication	Preclinical	Mfg	Phase 1	Phase 2	Phase 3
Bladder	HS-410 (vesigenurtacel-L)	BCG; Monotherapy	NMIBC					
	HS-110 (viagenpumatucl-L)	nivolumab and other checkpoint inhibitors	NSCLC					
Lung	HS-110 (viagenpumatucl-L)	cyclophosphamide	NSCLC					



>1,000 doses administered in approximately 200 patients

# Pipeline

## ImPACT

	Product	Combination	Indication	Preclinical	Mfg	Phase 1	Phase 2	Phase 3
Bladder	HS-410 (vesigenurtacel-L)	BCG; Monotherapy	NMIBC					
Lung	HS-110 (viagenpumatucl-L)	nivolumab and other checkpoint inhibitors	NSCLC					
	HS-110 (viagenpumatucl-L)	cyclophosphamide	NSCLC					

 **HS-410 received fast track designation from U.S. FDA**

# Bladder Cancer – NMIBC Opportunity

## Large Market

- Over 500,000 bladder cancer patients in U.S.<sup>1</sup>
- 74,000+ new cases and 16,000 deaths per year in U.S.<sup>1</sup>

## High Unmet Medical Need

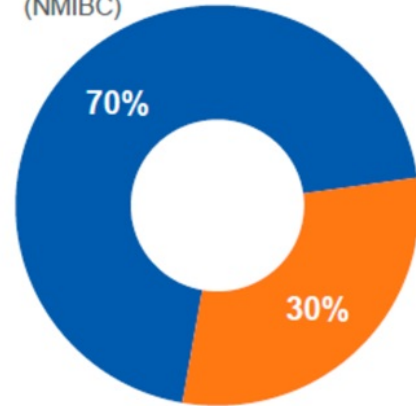
- No new NMIBC treatments in 25 years
- Prevent progression to MIBC
- Priority for FDA
- Highest lifetime treatment cost per patient of all cancers (\$96,000 to \$187,000 per individual per year in U.S.)<sup>2</sup>

## Ideal Setting

- Minimal residual disease
- Responsiveness to immunotherapy (BCG)<sup>3</sup>

## Bladder Cancer

Non-Muscle Invasive Bladder Cancer (NMIBC)



Muscle Invasive Bladder Cancer (MIBC)

# HS-410 Phase 1 NMIBC Trial Overview

- Design**
- Open-label, multicenter safety trial
  - Intradermal injections of HS-410 after surgery and induction BCG
  - 10 patients enrolled

- Safety**
- Positive safety profile
  - No SAEs or vaccine-related treatment discontinuations

- Immune Response**
- HS-410 shared 15+ tumor antigens in common with patients
  - Unprecedented increase in intratumoral CD8+ T cells following vaccination
  - Broad-based (polyclonal) expansion of patient T cells

- Efficacy**
- 7 of 10 patients no cancer recurrences >1 year after SOC surgery
  - 3 of 4 patients with CIS had complete response durable beyond one year<sup>1</sup>
  - Strong correlation between baseline characteristics of TILs by T cell receptor (TCR) sequencing and clinical outcome

Results

# High Degree of Overlap with Patient Tumor Antigens

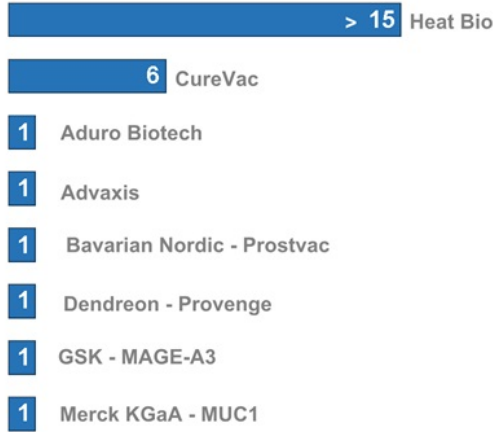
Heat's HS-410 shared at least 15 tumor antigens with those expressed on the patients' cancer cells

Heat's platforms target broad range of antigens

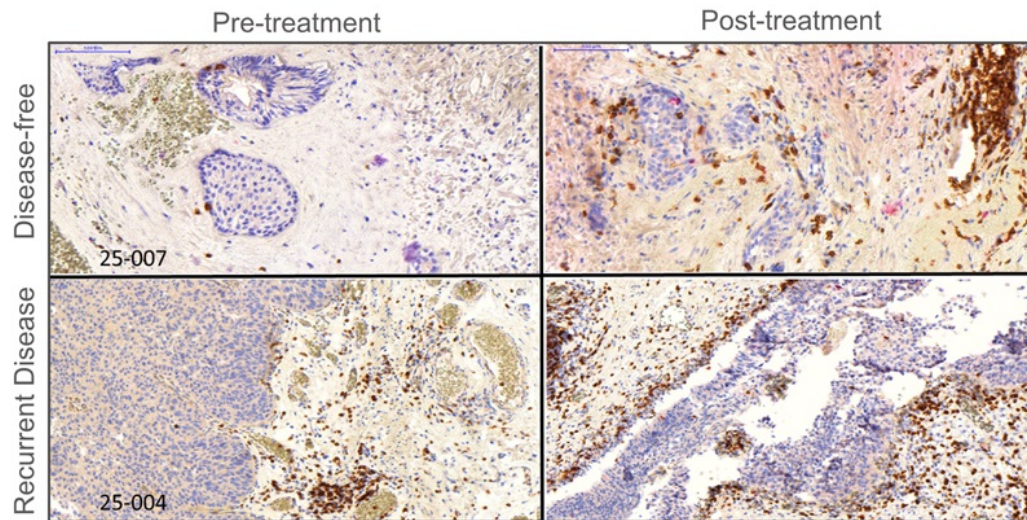
Antigen	Patient Samples							
	HS-410	23-002	25-001	25-004	25-005	25-003	25-007	25-008
ACTL8	+++	-	-	-	-	-	-	-
ADAM22	+++	+	+++	++	+++	+++	+++	+++
ADAM23	+++	+	++	+++	-	+++	+++	+++
ATAD2	+++	+++	+++	+++	+++	+++	+++	+++
ATAD2B	+++	+++	+++	+++	+++	+++	+++	+++
BIRC5	+++	+++	+++	-	-	++	++	+++
CASC5	+++	+++	+++	++	++	+++	+++	+++
CEP290	+++	+++	+++	++	+++	+++	+++	+++
CEP55	+++	+++	+++	++	++	+++	++	++
CTAGE5	+++	+++	+++	++	+++	+++	+++	+++
DCAF12	+++	+++	+++	-	+++	+++	+++	+++
DDX5	+++	+++	+++	-	+++	+++	+++	+++
FAM133A	+++	-	-	-	-	*	-	-
IL13RA2	+++	++	++	-	-	+	+++	-
IMP3	+++	+++	+++	-	+++	+++	+++	+++
KIAA0100	+++	+++	+++	-	+++	+++	+++	+++
MAGEA11	+++	*	+	+++	-	-	-	+
MAGEA3	+++	-	+	+++	-	+	-	++
MAGEA6	+++	-	+++	-	-	-	-	++
MPHOSPH10	+++	+++	+++	+++	+++	+++	+++	+++
ODF2	+++	+++	+++	++	+++	+++	+++	+++
ODF2L	+++	+++	+++	-	+++	+++	+++	+++
OIP5	+++	++	+	+++	+	+	++	+
PBK	+++	+++	+++	+++	-	+	+	++
RQCD1	+++	+++	+++	++	+++	+++	+++	+++
SPAG1	+++	++	+++	+++	+++	+++	+++	+++
SPAG4	+++	++	+++	-	++	++	+	++
SPAG9	+++	+++	+++	+++	+++	+++	+++	+++
TMEFF1	+++	-	+	-	-	-	-	-
TTK	+++	+++	+++	-	+	++	++	+

(-) < 5 Reads  
 (+) > 5 Normalized Reads  
 (++) > 25 Normalized Reads  
 (+++) > 100 Normalized Reads

## Number of Antigens Targeted

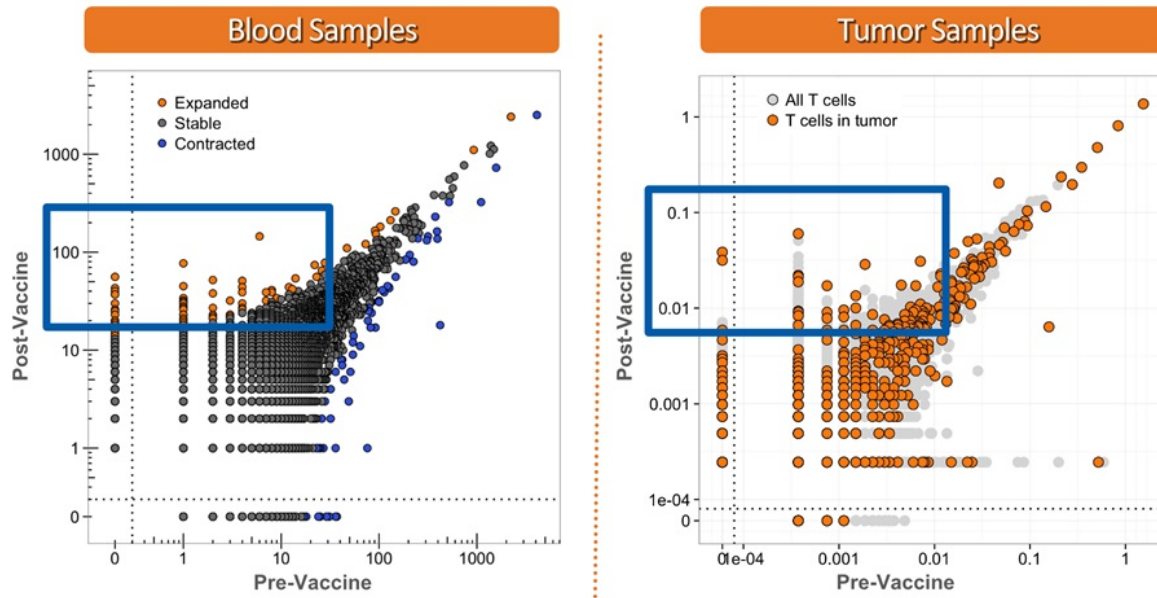


## Post-treatment Induction of CD8+ TIL



- Before treatment there are few CD8+ (red) TIL in the disease-free patient (25-007, upper left), whereas TIL are abundant in the recurring patient (25-004, lower left)
- Following treatment with HS-410, there is robust induction of TIL in the disease-free patient, with moderate induction in the recurring patient

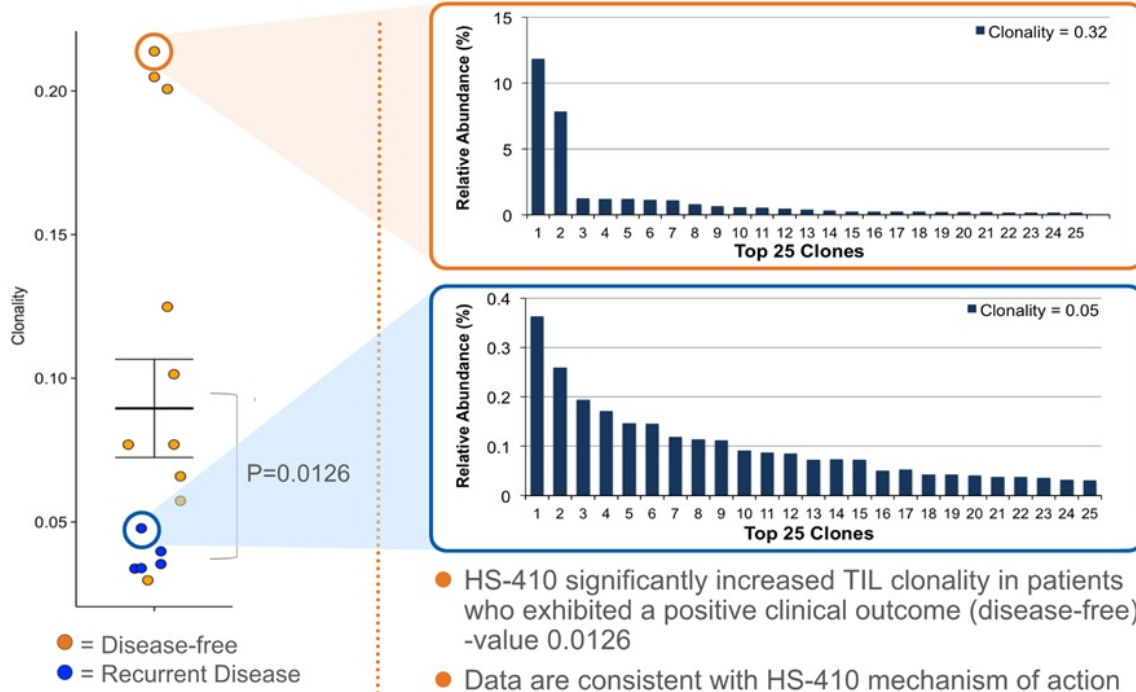
# Polyclonal TCR Expansion in Blood and Tumor Samples



**T cells that are expanding post-vaccine are those that were present at very low frequencies (or completely absent) in the pre-vaccine sample**



# Significant Correlation Between TIL Clonality and Clinical Outcome



- HS-410 significantly increased TIL clonality in patients who exhibited a positive clinical outcome (disease-free); P-value 0.0126
- Data are consistent with HS-410 mechanism of action

# HS-410 Ph 2 NMIBC Trial Overview

**Objective**

- Evaluate safety and tolerability of HS-410 either alone or in combination with BCG

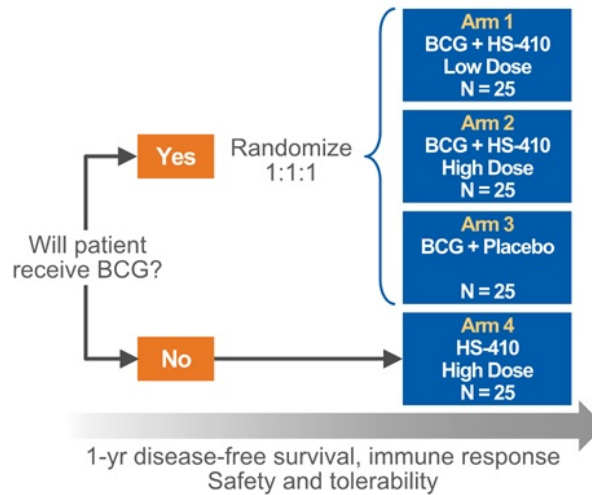
**Patient Population**

- Patients with NMIBC (high-grade Ta; T1; CIS) after surgery

**Enrollment**

- 16 U.S. sites
- Completed enrollment of 75 patients for randomized arms; 16 patients enrolled for monotherapy arm<sup>1</sup>

## Phase 2 Randomized Controlled



**Topline data expected 4Q:16**

15 1. As announced on February 25, 2016, no new patients will be enrolled in the monotherapy trial arm following resolution of the BCG shortage and recent discussions with FDA.

## HS-410 Ph 2 NMIBC Monotherapy 3-Month Interim Data

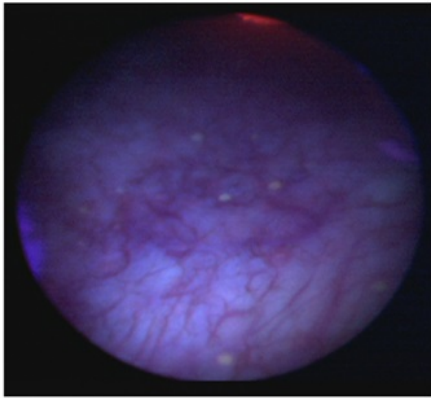


### 3-mo recurrence rate (RR) – combo arms still blinded

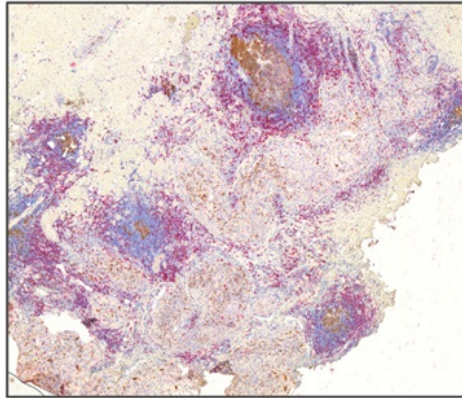
Population	Historical RR <sup>1</sup>	Monotherapy RR
High-risk papillary only	~20%	1/6 (17%)
<b>CIS</b>	<b>~50%</b>	<b>0/1 (0%)</b>
Intermediate risk	UNK (~<20%)	N/A
Composite	~30%	1/7 (14%)

- No recurrences to date beyond six months in either the Ph 1 or Ph 2 monotherapy trials
- Six different investigators performing cystoscopies have commented:
  - *“The bladders look different...bumpy...nodular...”*

## HS-410 Ph 2 NMIBC Monotherapy 3-Month Interim Data



Blue-light cystoscopy from patient treated with HS-410



Tumor biopsy from patient treated with HS-410

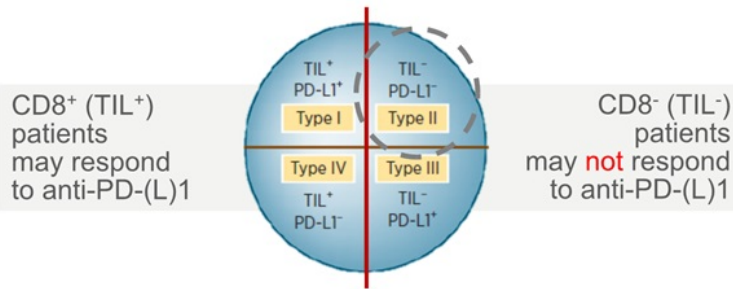
- Images of the bladder (above) showed changes that resemble lymphoid (T cell rich) structures, which we believe indicates that HS-410 leads to a localized immune response within the bladder

# Pipeline

## ImPACT

	Product	Combination	Indication	Preclinical	Mfg	Phase 1	Phase 2	Phase 3
Bladder	HS-410 (vesigenurtacel-L)	BCG; Monotherapy	NMIBC					
Lung	HS-110 (viagenpumatucl-L)	nivolumab and other checkpoint inhibitors	NSCLC					
	HS-110 (viagenpumatucl-L)	cyclophosphamide	NSCLC					

# NSCLC Opportunity



Approx. 50% PD-1 ORR

Approx. 10% PD-1 ORR

**Estimated 45% NSCLC patients being underserved by single-agent anti-PD-(L)1 may benefit from vaccine combination**

# HS-110 Ph 1b NSCLC “DURGA” Trial Overview

**Objective**

- Evaluate safety and tolerability of HS-110 + a PD-1 checkpoint inhibitor

**Patient Population**

- Potential to expand each cohort up to 30 patients<sup>1</sup>

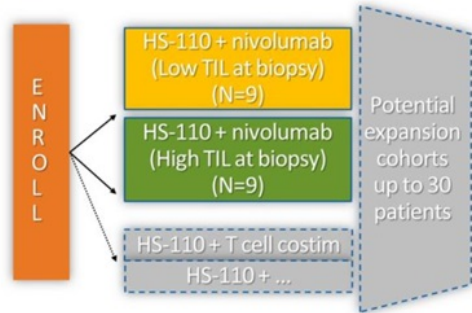
**Secondary Endpoints**

- Immune response, overall response rate, overall survival and progression-free survival

**Enrollment**

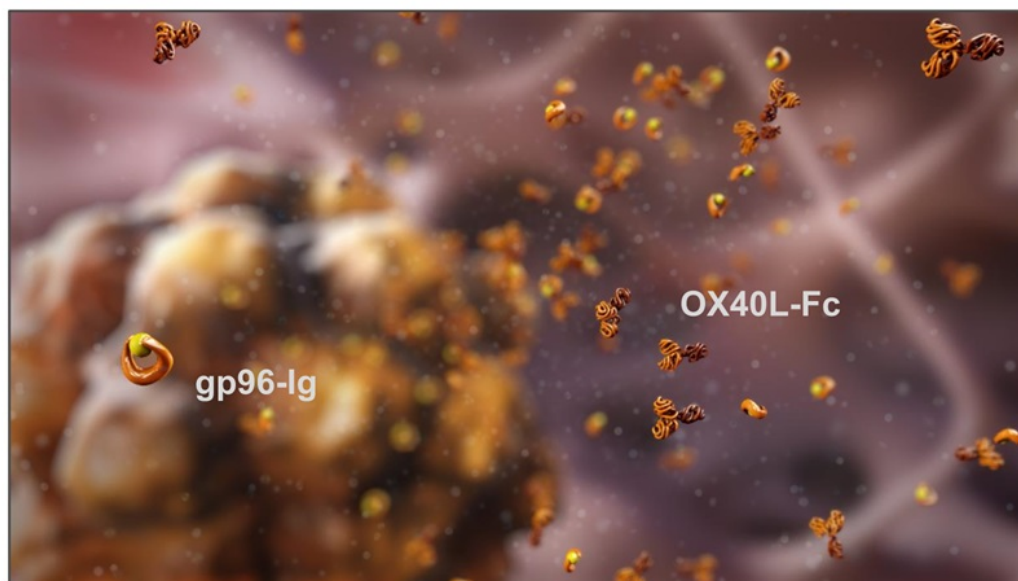
- 5 – 10 U.S. sites
- Partnership with Yale Cancer Center on TIL analysis

## One Year Topline Data Expected 4Q:16



*HS-110 weekly intradermally for 18 weeks;  
nivolumab i.v. every other week until progression*

## ComPACT Platform Technology

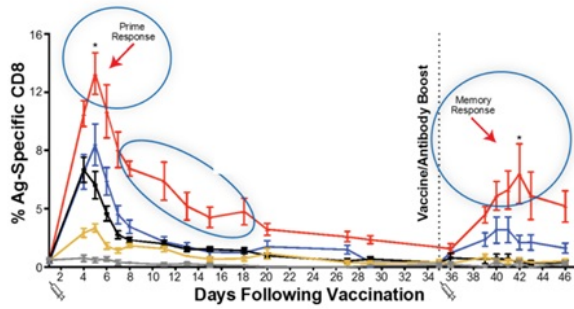


**>>> The first potential dual-acting immunotherapy designed to deliver T cell activation and costimulation in a single product – combination therapy without additive costs**

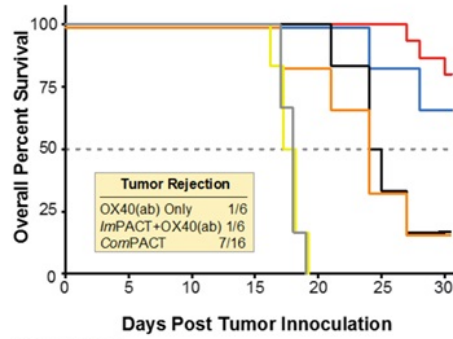




# ComPACT Outperforms OX40 Monoclonal Antibodies in Preclinical Models



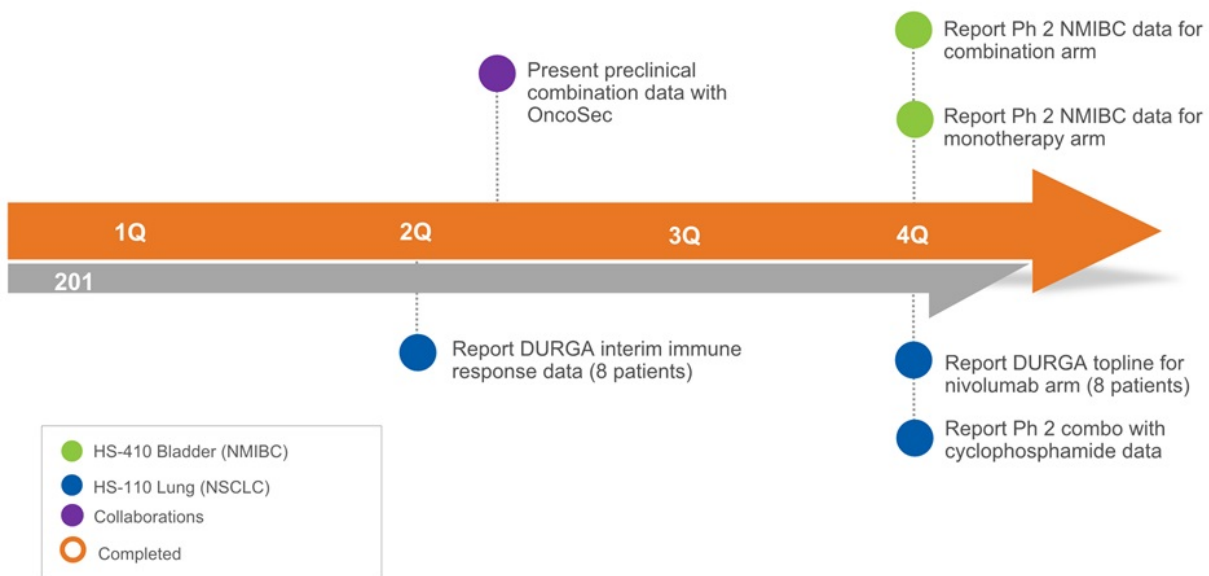
—●— Untreated (N=6)      —●— *ImPACT* (N=6)  
 —●— CT26 Only Control (N=6)      —●— *ImPACT* + OX40(ab) (N=6)  
 —●— OX40(ab) Only (N=6)      —●— *ComPACT* (N=6)



Tumor Rejection	
OX40(ab) Only	1/6
<i>ImPACT</i> +OX40(ab)	1/6
<i>ComPACT</i>	7/16

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

# 2016 Development Milestones



## Summary: Value Proposition

### Highlights:

- √ Clinical evidence of mechanism of action
- √ Favorable safety profile to-date
- √ Pan-antigen, T cell activation
- √ Applicable to multiple cancers
- √ Ready-to-use; scalable, low cost manufacturing
- √ Retain worldwide commercialization rights

### Upcoming Milestones:

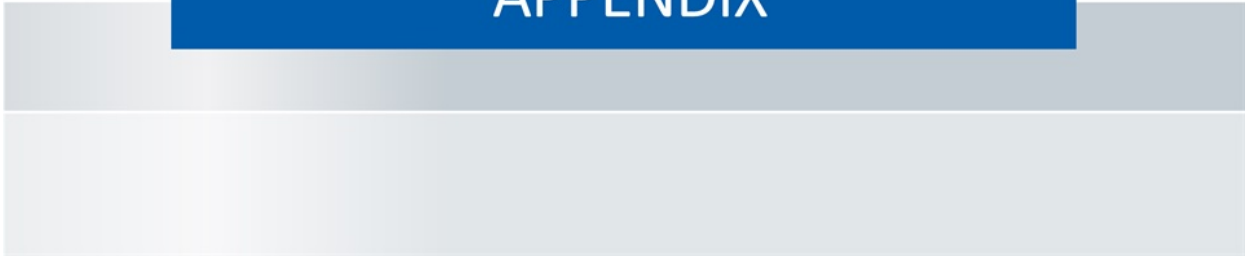
- Randomized Ph 2 HS-410 bladder data
- Monotherapy Ph 2 HS-410 bladder data
- Ph 1b HS-110 + PD-1 checkpoint inhibitor combination data (8 patients)
- Ph 2 HS-110 + cyclophosphamide data

The logo for Heat Biologics, featuring a stylized sun with a large orange-yellow circle on the left and a series of smaller yellow dots forming an arc above the text. The text "Heat Biologics" is written in a bold, blue, sans-serif font.

# Heat Biologics

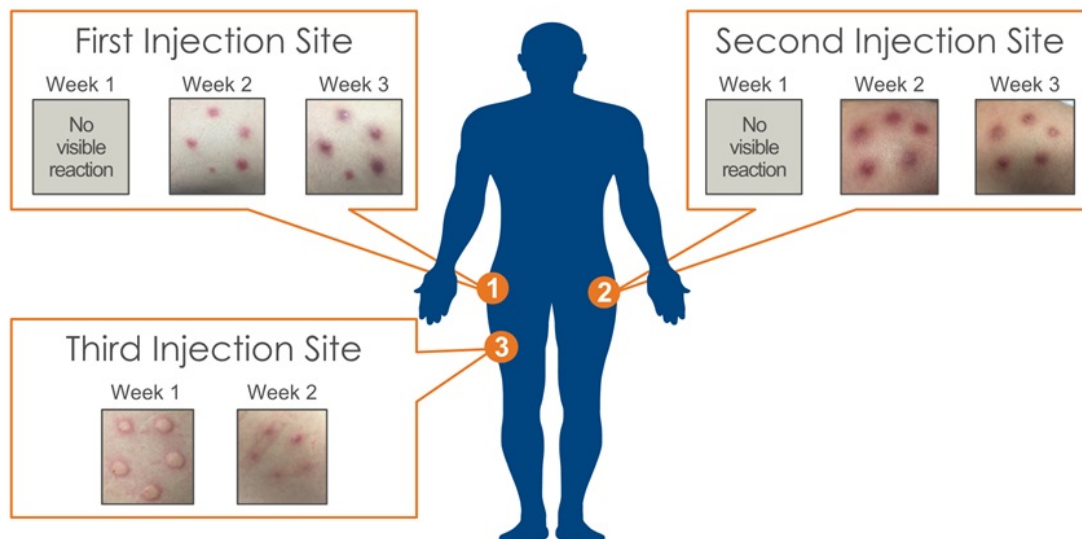
A blue rounded rectangular bar containing the word "APPENDIX" in white, uppercase, sans-serif font.

## APPENDIX



# HS-410 Injection Site Reactions

Kinetics Follow Delayed-type Hypersensitivity Reaction;  
Consistent with Mechanism of Action



## Clinical and Immune Response

### Disease Characteristics and Recurrence Status

Patient	T-Class	CIS	Grade	Disease Status	Induction BCG	Vaccine Doses	Maintenance BCG	3-month Cysto	6-month Cysto	Recurrence Status
12-001	T1	No	High	Newly Diagnosed	5	15	4			No
23-001	T1	Yes	High	Newly Diagnosed	6	15	3			No
23-002	T1	No	High	Newly Diagnosed	6	15	6		TIS	Yes
25-001	TA	No	High	Recurrent	3	6	0	TIS High		Yes
25-002	T1	Yes	High	Newly Diagnosed	3	15	3			No
25-003	T1	No	High	Newly Diagnosed	6	15	0			No
25-004	T1	Yes	High	Newly Diagnosed	5	12	0	Ta high	T1 high CIS	Yes
25-005	T1	No	High	Newly Diagnosed	6	15	2	Ta low		No
25-007	T1	No	High	Newly Diagnosed	6	15	0			No
25-008	TIS	Yes	High	Newly Diagnosed	6	15	0			No

- 7 out of 10 patients had no documented recurrence of cancer >1 year after standard of care surgery
- 3 out of 4 patients with *carcinoma in situ* (CIS), the patient population least responsive to standard of care BCG, did not recur

The logo for Heat Biologics, featuring a stylized sun with a large orange-yellow sphere on the left and a series of smaller yellow dots forming an arc above the text. The text "Heat Biologics" is written in a bold, blue, sans-serif font.

# Heat Biologics

THANK YOU



