
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): **June 6, 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))
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-

Item 7.01. – Regulation FD Disclosure.

Heat Biologics, Inc. (the “Company”) updated its corporate presentation to reflect the recent data reported for its Phase 1b study of HS-110 in combination with anti-PD-1 checkpoint inhibitor, nivolumab, for the treatment of non-small cell lung cancer. This presentation will be used in discussions with investors and is furnished 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.

In addition, attached as Exhibit 99.2 to this Current Report on Form 8-K is a press release, dated June 6, 2016, regarding the Company’s Phase 1b study of HS-110 in combination with anti-PD-1 checkpoint inhibitor, nivolumab, for the treatment of non-small cell lung cancer.

The information included in this Item 7.01 and in Exhibits 99.1 and 99.2 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 Current Report on Form 8-K or any of the Exhibits.

Item 9.01. – Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed as part of this Report.

99.1	Presentation materials to be provided at Heat Biologics, Inc. presentations
99.2	Press Release issued by Heat Biologics, Inc., dated June 6, 2016



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: June 6, 2016

HEAT BIOLOGICS, INC.

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



EXHIBIT INDEX

Exhibit Number	Description
99.1	Presentation materials to be provided at Heat Biologics, Inc. presentations
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NASDAQ:HTBX

June 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*

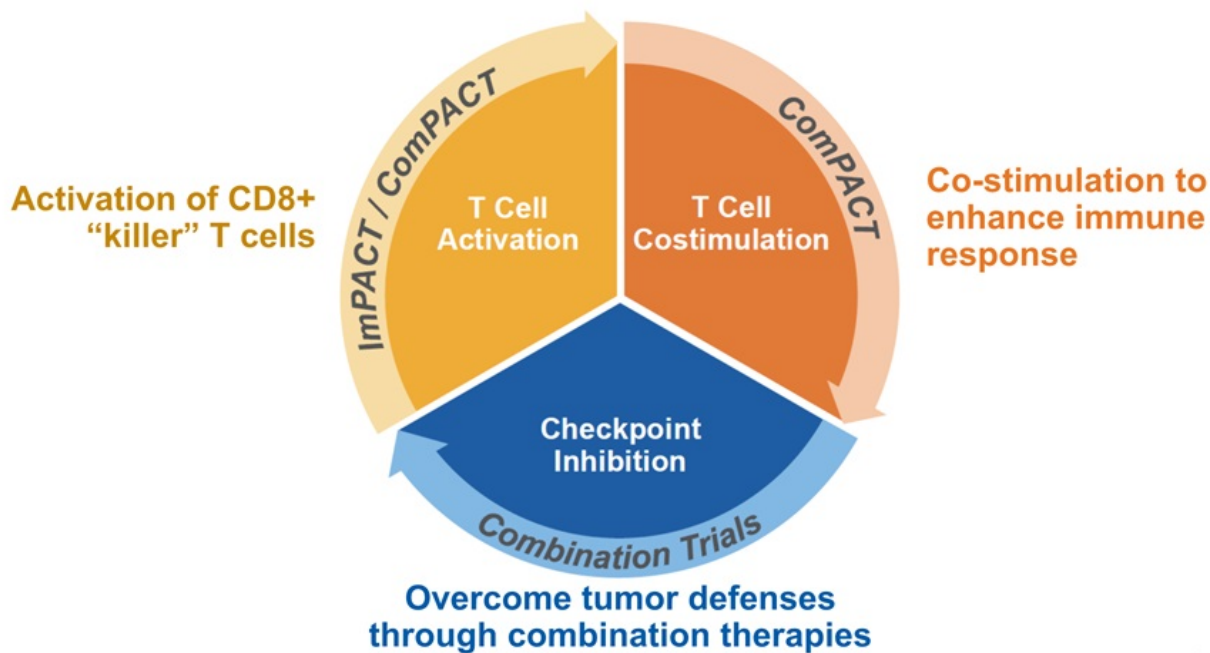
Developing first new immunotherapy
in non-muscle invasive bladder
cancer (NMIBC)

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

Cancer Cell
Lines & Patient
Samples



Heat's Antigen
Screening &
Selection Algorithm



Select Cell Line
with Most Antigen
Overlap



Transfect with
Heat's
Technology



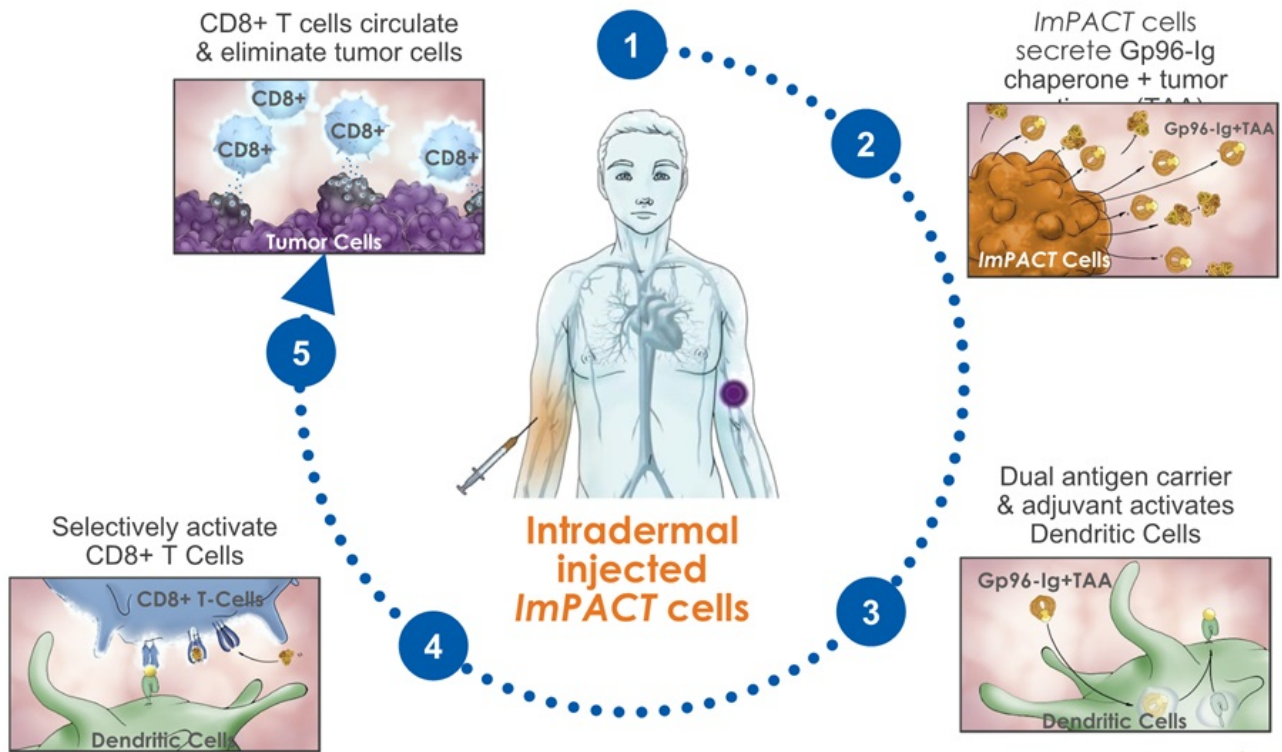
Transition to CMO
to Mass Produce



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

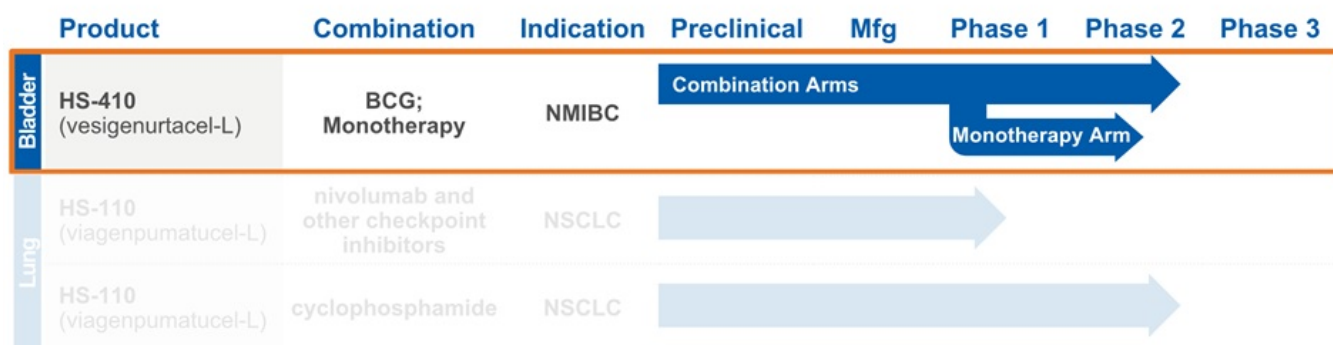
ImPACT

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

>1,000 doses administered in approximately 200 patients

Pipeline

ImPACT



 **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.¹
- 74,000+ new cases and 16,000 deaths per year in U.S.¹

High Unmet Medical Need

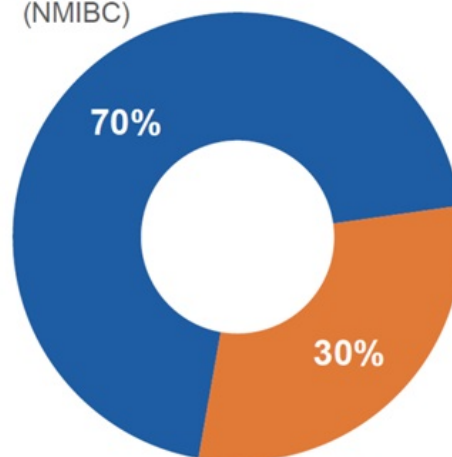
- No new NMIBC treatments in 25 years
- Prevent progression to MIBC
- Priority for FDA
- Highest lifetime treatment cost per patient of all cancers (\$96,000 to \$187,000 per individual per year in U.S.)²

Ideal Setting

- Minimal residual disease
- Responsiveness to immunotherapy (BCG)³

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 C/S had complete response durable beyond one year¹
- Strong correlation between baseline characteristics of TILs by T cell receptor (TCR) sequencing and clinical outcome

Results

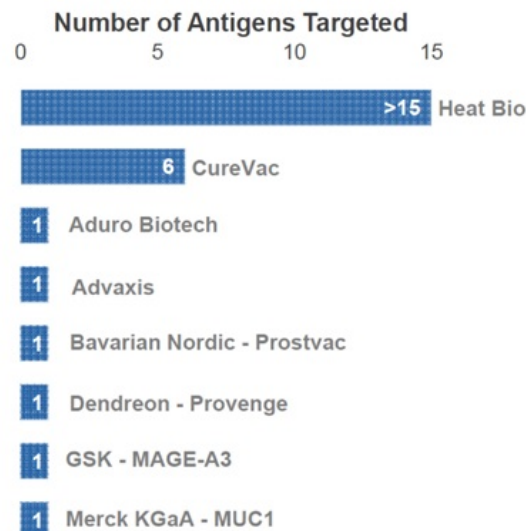
High Degree of Overlap with Patient Tumor Antigens

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

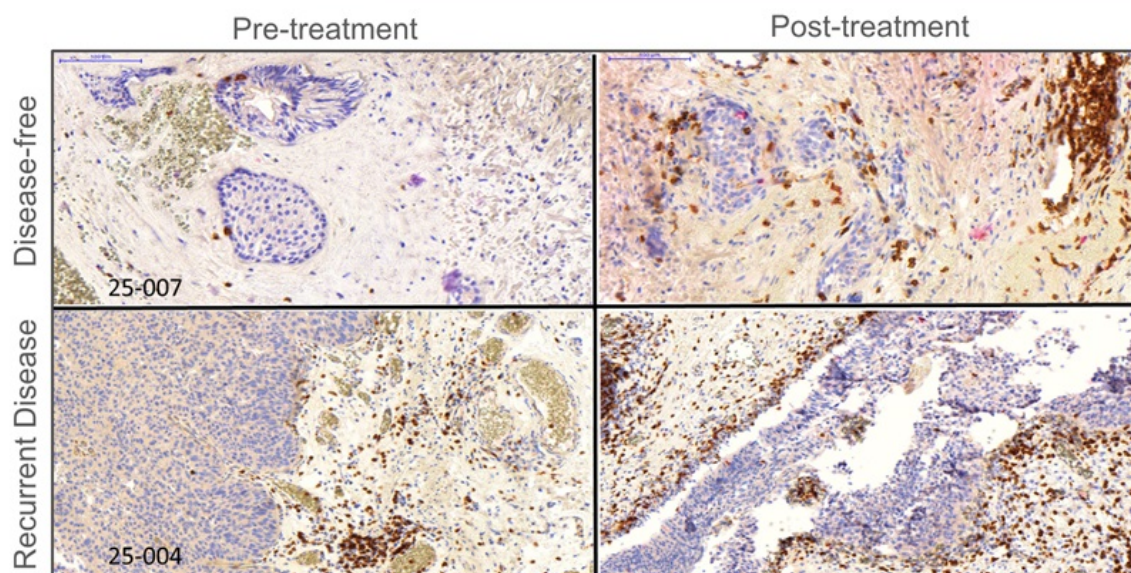
Antigen	Patient Samples							
	HS-410	23-002	25-001	25-004	25-005	25-003	25-007	25-008
ACTL8	+++	---	---	---	---	---	---	---
ADAM22	+++	+++	+++	++	+++	+++	+++	+++
ADAM23	+++	+	++	+++	---	+++	+++	+++
ATAD2	+++	+++	+++	---	+++	+++	+++	+++
ATAD2B	+++	+++	+++	---	+++	+++	+++	+++
BIRC5	+++	+++	+++	---	---	++	++	+++
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

Heat's platforms target broad range of antigens

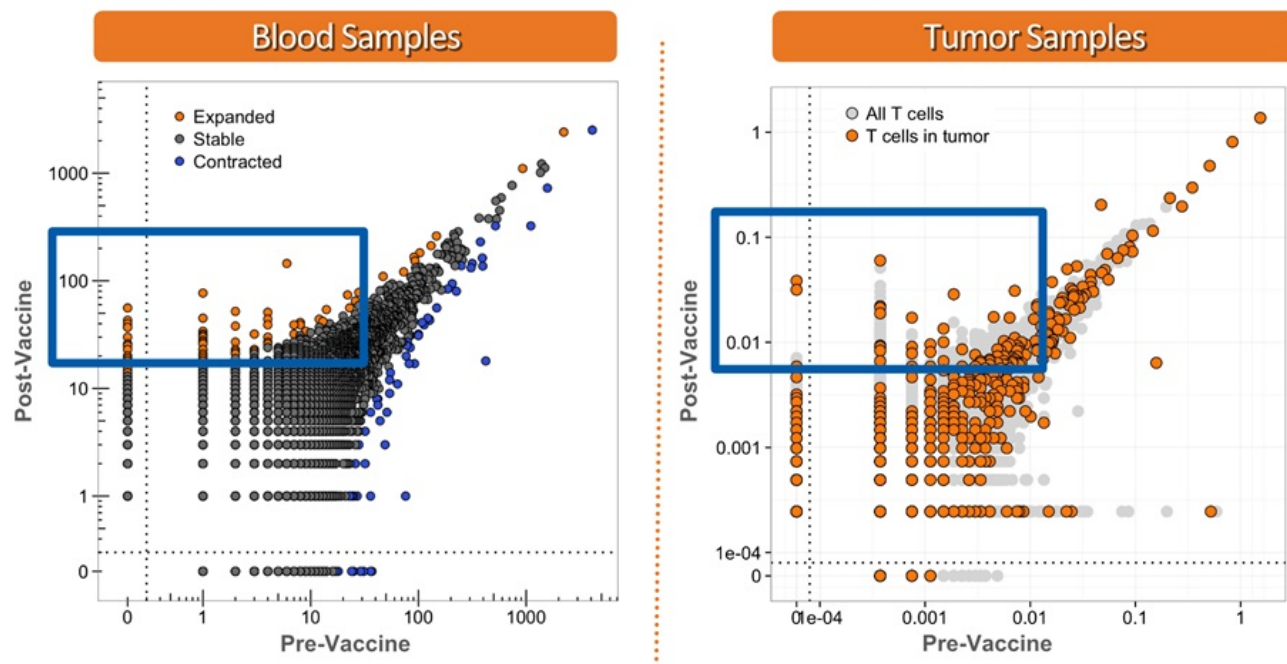


Post-treatment Induction of CD8+ TIL



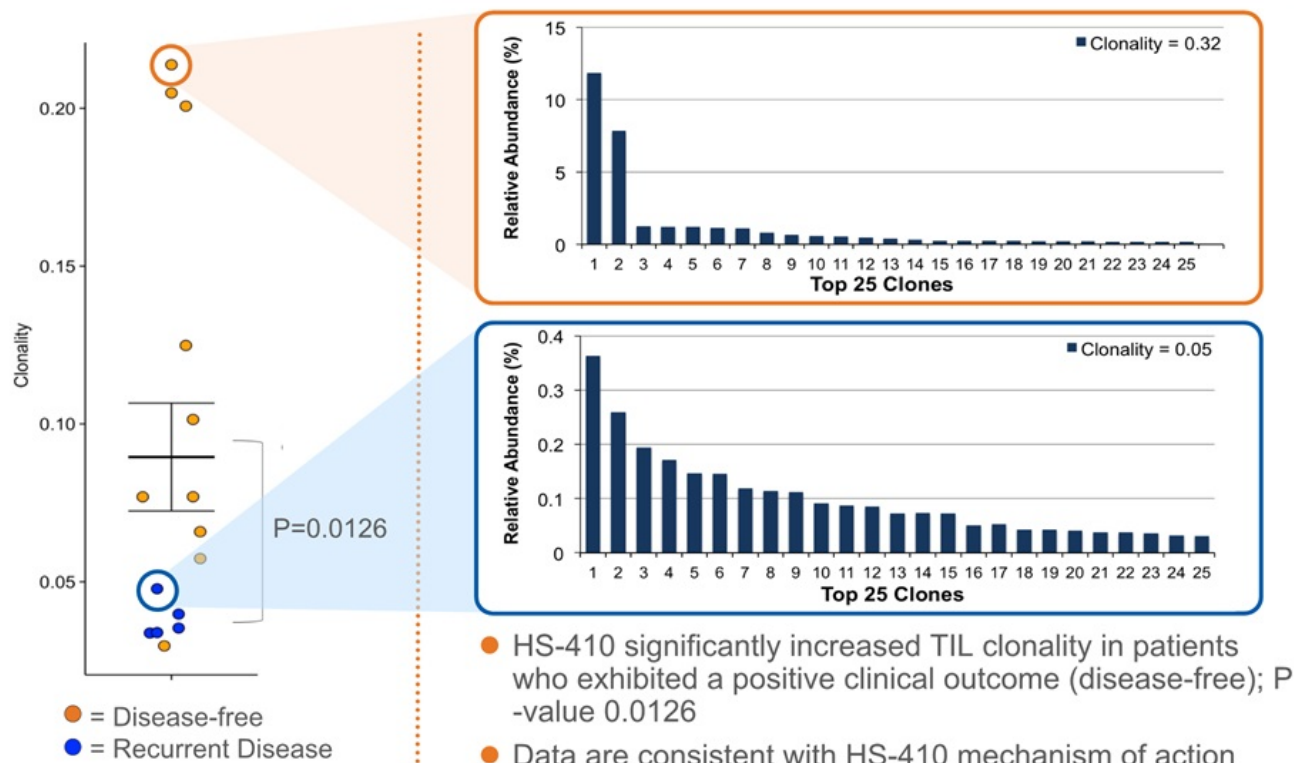
- Before treatment there are few CD8+ (red) TIL in the disease-free patient (25-007, upper left), whereas TIL are abundant in the recurring patient (25-004, lower left)
- Following treatment with HS-410, there is robust induction of TIL in the disease-free patient, with moderate induction in the recurring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

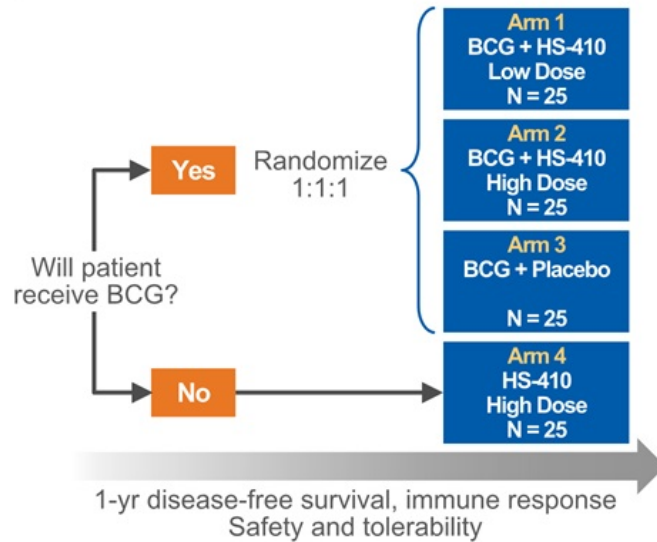
Patient Population

- 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 arm¹

Phase 2 Randomized Controlled



Topline data expected 4Q:16

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

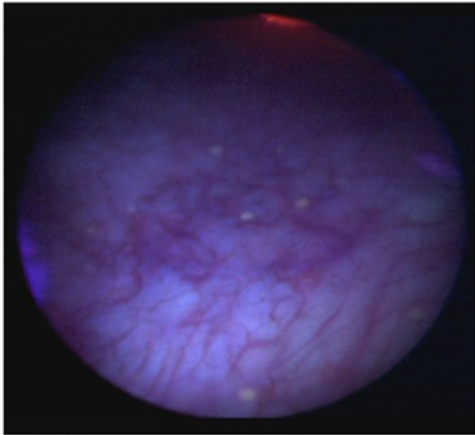


3-mo recurrence rate (RR) – combo arms still blinded

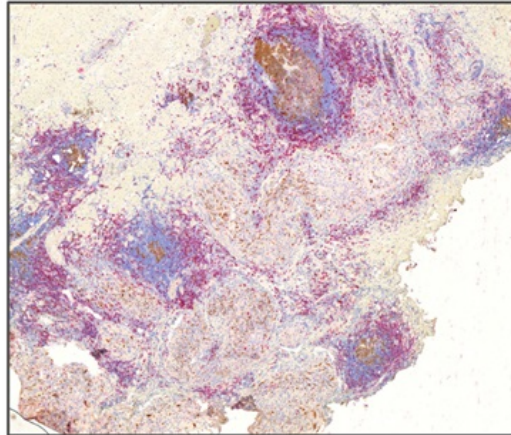
Population	Historical RR ¹	Monotherapy RR
High-risk papillary only	~20%	1/6 (17%)
CIS	~50%	0/1 (0%)
Intermediate risk	UNK (~<20%)	N/A
Composite	~30%	1/7 (14%)

- 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

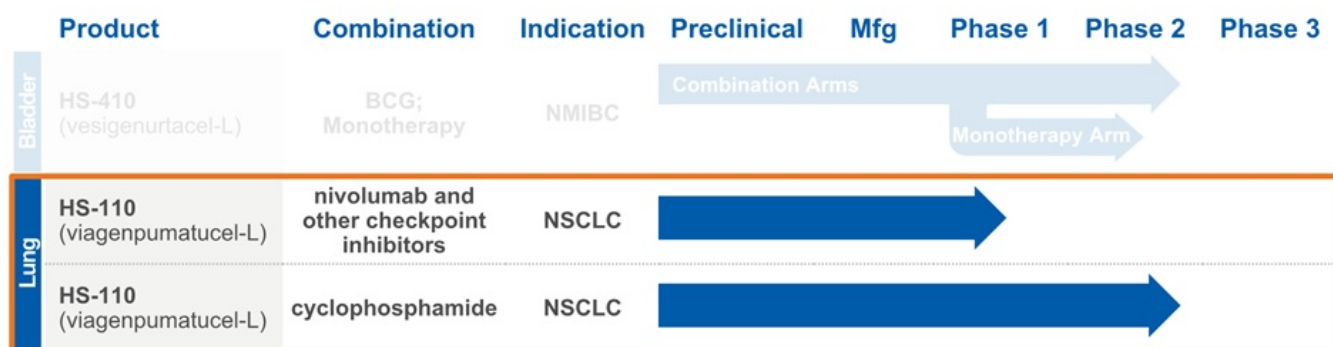


Tumor biopsy from patient treated with HS-410

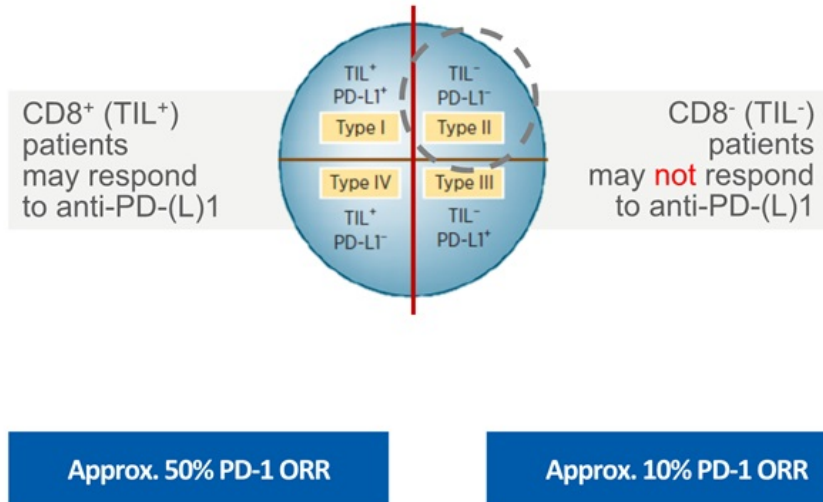
- Images of the bladder (above) showed changes that resemble lymphoid (T cell rich) structures, which we believe indicates that HS-410 leads to a localized immune response within the bladder

Pipeline

ImPACT



NSCLC Opportunity



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 patients¹

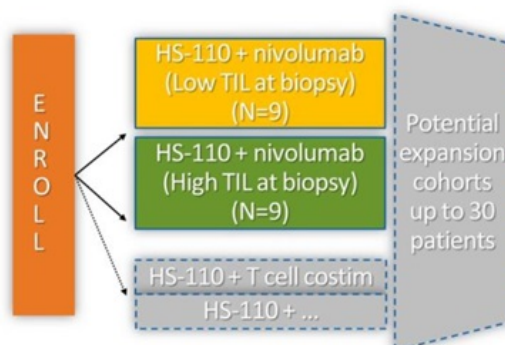
Secondary Endpoints

- 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

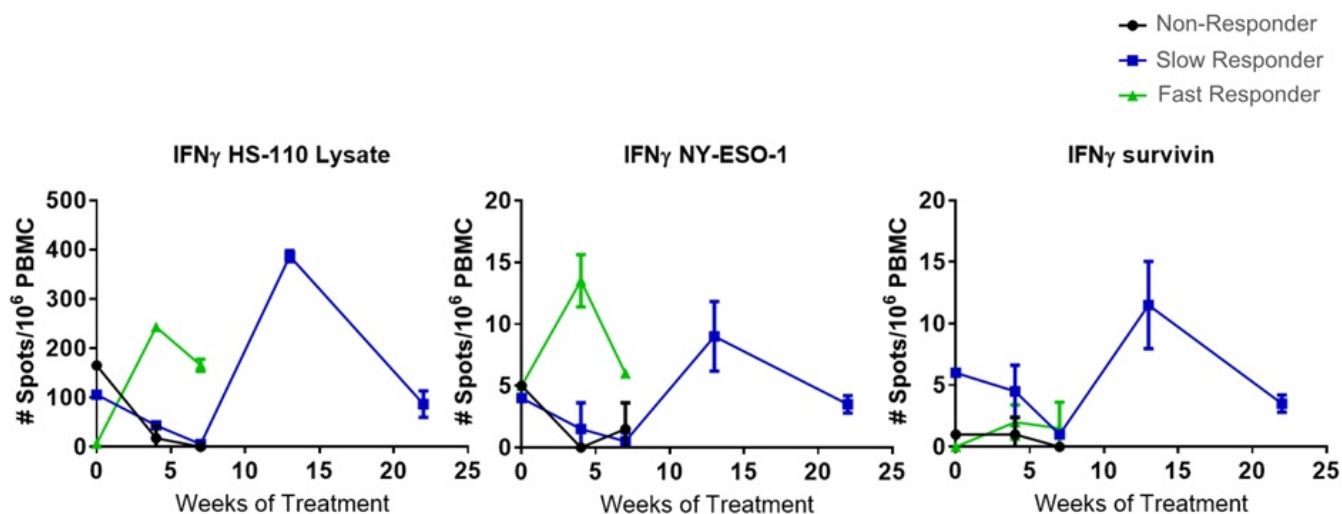


HS-110 weekly intradermally for 18 weeks;
nivolumab i.v. every other week until progression

HS-110 DURGA Patient Case Studies

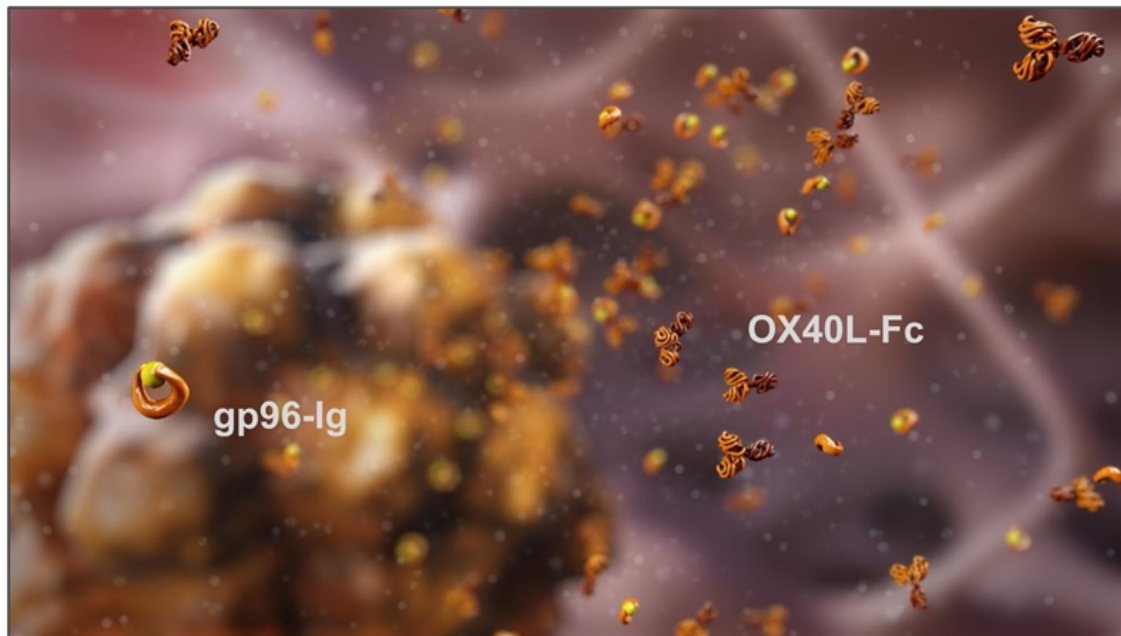
	Patient 1 "Non-Responder"	Patient 2 "Slow Responder"	Patient 3 "Fast Responder"
Baseline TIL	High CD8+ TIL (>10%) moderate PD-L1	Low CD8+ TIL (≤10%)* low PD-L1	Low CD8+ TIL ,* low PD-L1
Exposure	6 doses of HS-110 3 doses of nivolumab	17 doses of HS-110 9 doses of nivolumab (completed study)	14 doses of HS-110 7 doses of nivolumab (ongoing)
Injection Site Reactions	None	Yes , most doses Plus maculopapular rash on chest	Yes , most doses Plus maculopapular rash under arms
Tumor Response	Progressive Disease at Week 6 scan (504% increase)	Stepwise tumor reduction (Partial Response -6%→ -18%→ -42%) Time to PR: 122 days	Rapid tumor reduction (PR (-50%) at Week 10) Time to response: 72 days
Post-treatment TIL	Not done due to progression	High CD8+ TIL , moderate PD-L1	High CD8+ TIL ,* PD-L1 not evaluable

Immune Response in DURGA Case Studies



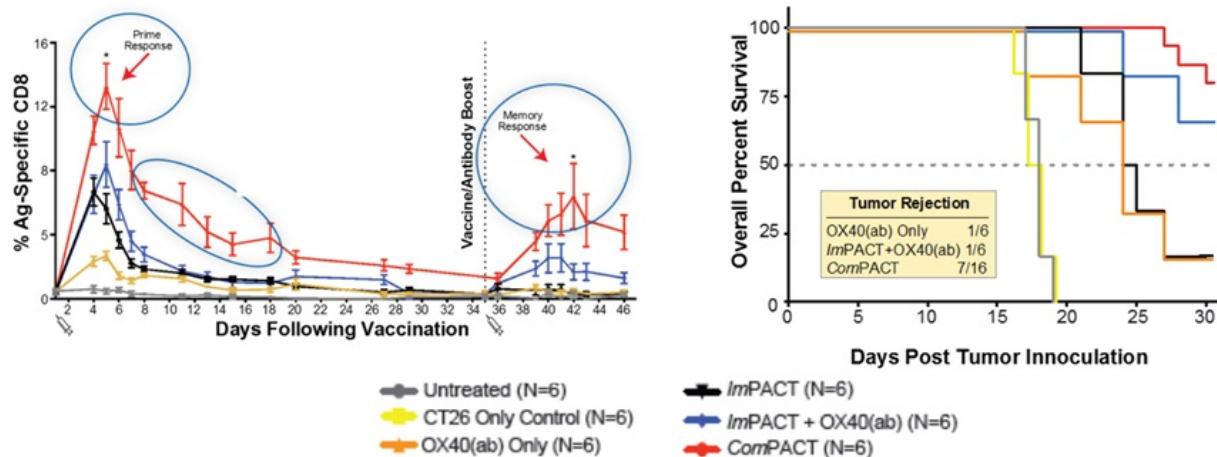
ELISPOT analysis of patient blood samples demonstrated induction of antigen-specific immune responses to both total vaccine antigen and individual shared tumor antigens in both responding patients, but not the clinical non-responder.

ComPACT Platform Technology



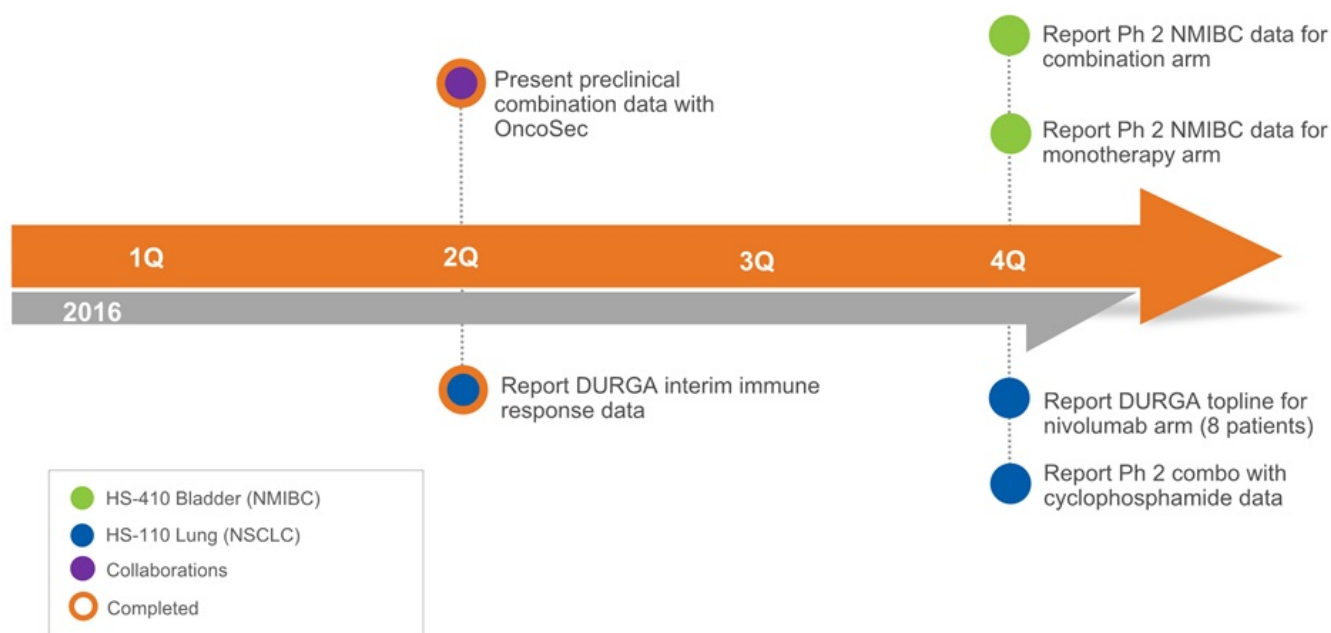
The first potential dual-acting immunotherapy designed to deliver T cell activation and costimulation in a single product – combination therapy without additive costs

ComPACT Outperforms OX40 Monoclonal Antibodies in Preclinical Models



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

2016 Anticipated 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 Anticipated 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



Heat Biologics

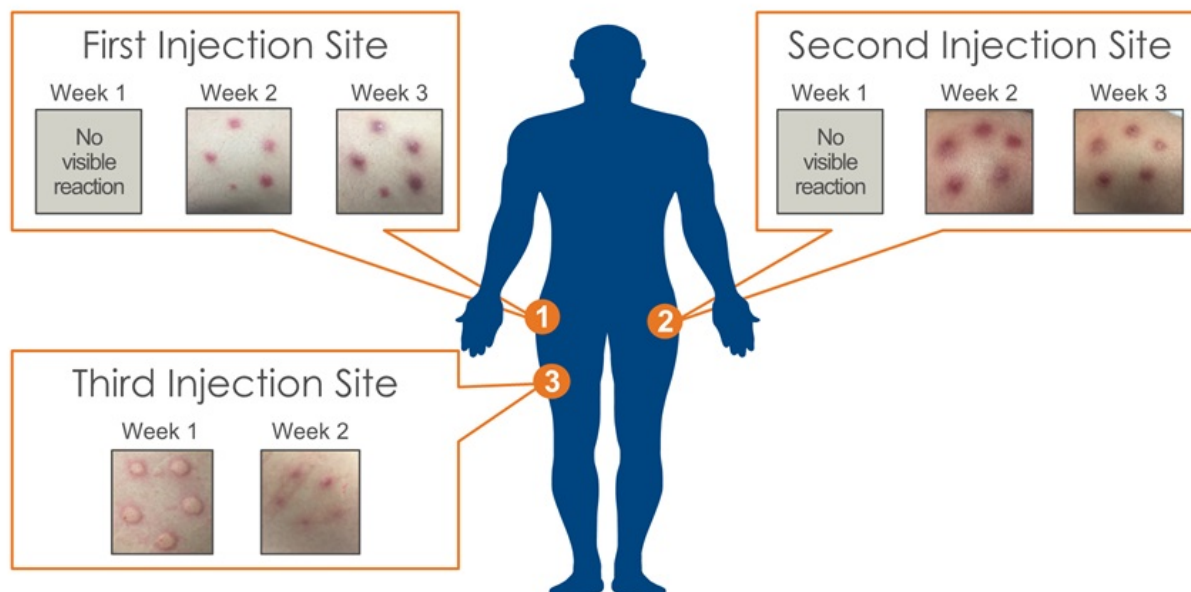


APPENDIX



HS-410 Injection Site Reactions

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



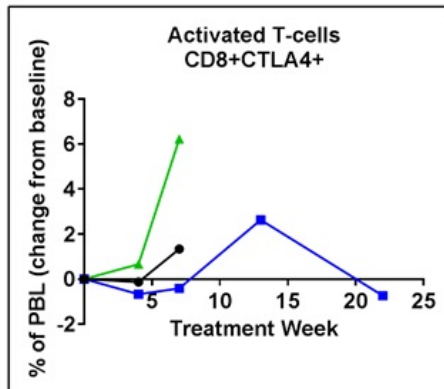
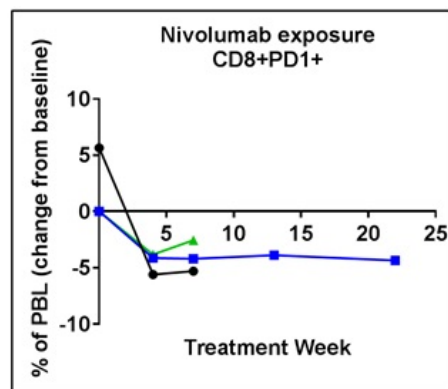
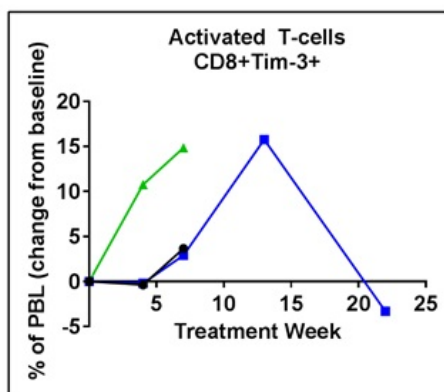
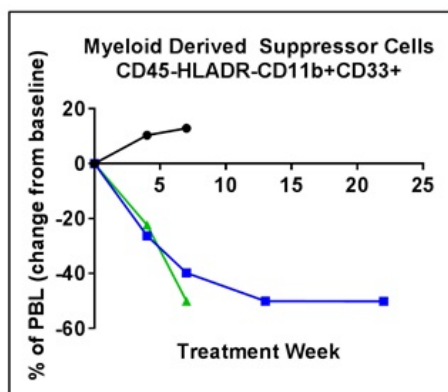
Clinical and Immune Response

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

Interim Immune Response in DURGA Case Studies



- Non responder
- Slow responder
- Fast responder

- Responding patients showed a rapid decrease in immunosuppressor cells by flow cytometry (such as MDSC, top left panel), and stable increases in activated effector T cells (right panels).
- All three patients showed a decrease in immune cell PD-1 expression consistent with nivolumab's mechanism of action



THANK YOU



Heat Biologics Presents a Poster on its HS-110/Nivolumab Combination Phase 1b Non-Small Cell Lung Cancer Trial at ASCO Annual Meeting

- *Poster reviews trial design and endpoints*
- *Additional data illustrates clinical and immune response correlation*

DURHAM, NC, June 6, 2016 – [Heat Biologics, Inc.](http://www.heatbio.com) (Nasdaq: HTBX), an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer, announced that it presented a poster entitled "Broadening response rates to PD-1 therapy in advanced lung adenocarcinoma: Viagenpumatucel-L (HS-110) in combination with nivolumab in the ongoing DURGA trial" (Abstract #TPS9102) at the American Society of Clinical Oncology (ASCO) Annual Meeting. The poster was accepted within the Trials in Progress category and as such, reviewed the design and endpoints for the ongoing Phase 1b study of HS-110 in combination with anti-PD-1 checkpoint inhibitor, nivolumab, for the treatment of non-small cell lung cancer (NSCLC). Eight patients are currently enrolled.

Recent study findings, not presented at ASCO, suggest that the addition of HS-110 to nivolumab does not significantly alter the nivolumab safety profile to-date. In addition, case studies of three trial patients (one non-responder and two responders) have been characterized. While all three patients showed a decrease in immune cell PD-1 expression, which is consistent with nivolumab's mechanism of action, both responders also showed a decrease in immunosuppressor cells, as well as increases in activated effector T cells in the peripheral blood. Furthermore, the two responders showed an increase in CD8+ T cells in biopsy samples after treatment with the HS-110/nivolumab combination. ELISPOT analysis of patient blood samples demonstrated induction of antigen-specific immune responses to both total vaccine antigen and individual shared tumor antigens in both responding patients, but not the clinical non-responder. Finally, these responding patients also had low-grade injection site reactions in addition to rash, which the non-responder did not, suggesting their clinical and immune responses may be attributed to the HS-110 vaccine.

These data are included in the updated corporate presentation which is available on Heat's corporate website at www.heatbio.com. As previously announced, full topline data on all eight patients is expected to be presented in the fourth quarter, including all primary and secondary endpoints.

"In these early data, we observed a correlation between patients' clinical outcomes and their immunological responses, which we believe indicates that tumor response may be a result of increased immunological activity," said Melissa Price, Ph.D., Heat's VP of Product Development. "Additionally, the two responders qualitatively converted from low to high tumor infiltrating lymphocytes (TILs), which is consistent with data previously reported from our bladder cancer study. This finding supports our hypothesis that patients with low levels of TILs, who typically do not respond well to single-agent checkpoint inhibitors, may respond to a combination with our *ImPACT* vaccine."



About Heat Biologics, Inc.

Heat Biologics, Inc. (Nasdaq: HTBX) is an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer. Heat's highly specific T cell-stimulating platform technologies, *ImPACT* and *ComPACT*, form the basis of its product candidates. These platforms, in combination with other therapies, such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms of action: robust activation of CD8+ "killer" T cells (one of the human immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance patients' immune response. Currently, Heat is conducting a Phase 2 trial with its HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC) and a Phase 1b trial with its HS-110 (viagenpumatucl-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC). For more information, please visit www.heatbio.com.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 about Heat's 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, expectations and assumptions and include statements regarding the suggestion that the addition of HS-110 to nivolumab does not significantly alter the nivolumab safety profile to-date, the suggestion that the patients' clinical and immune responses may possibly be attributed to the HS-110 vaccine, timing of presentation of full topline data on all eight patients in the fourth quarter, the correlation between patients' clinical outcomes and their immunological responses, indicating that tumor response may be a result of increased immunological activity, the findings supporting the hypothesis that patients with low levels of TILs, who typically do not respond well to single-agent checkpoint inhibitors, may respond to a combination with Heat's *ImPACT* vaccine and the potential of Heat's *ImPACT* and *ComPACT* therapies. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of Heat's *ImPACT* and *ComPACT* therapies to perform as designed, the ability to enroll patients and complete the clinical trials on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2015 and our other filings with the SEC, including subsequent periodic reports on Forms 10-Q and 8-K. The information in this release is provided only as of the date of this release, and we undertake 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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