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): **November 9, 2015**

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(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 using an updated corporate presentation for investor meetings. In connection with the presentations, the Company intends to discuss the slide presentation 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 a 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.

Exhibit Number	Description
99.1	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: November 9, 2015

HEAT BIOLOGICS, INC.

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

EXHIBIT 99.1

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, 2014 and our quarterly report on Form 10-Q for the subsequent quarters (collectively, our “SEC Filings”). In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation, except as required by law.

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

Investment Opportunity

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

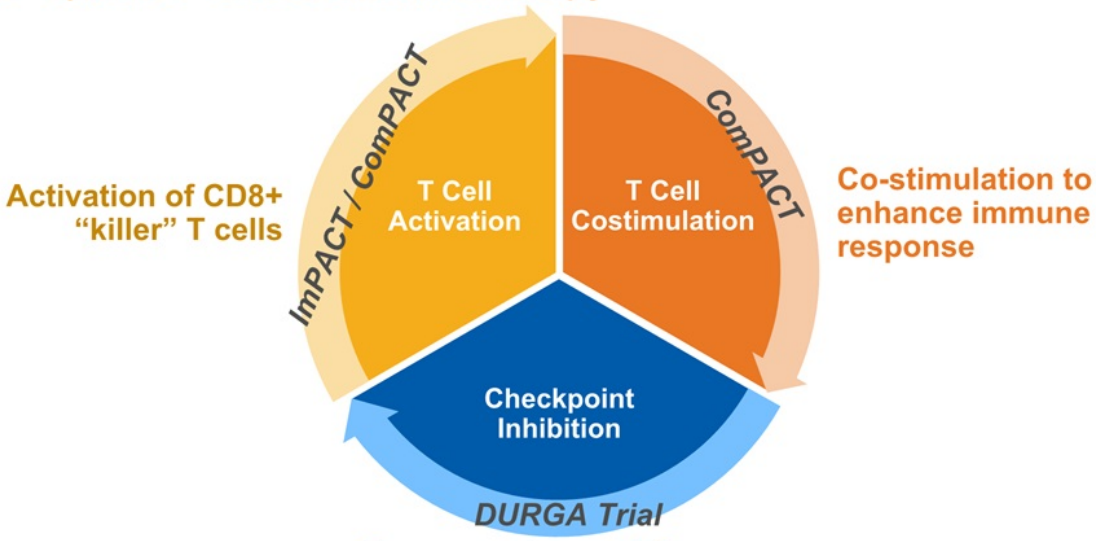
Developing first new immunotherapy in non-muscle invasive bladder cancer (NMIBC)

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

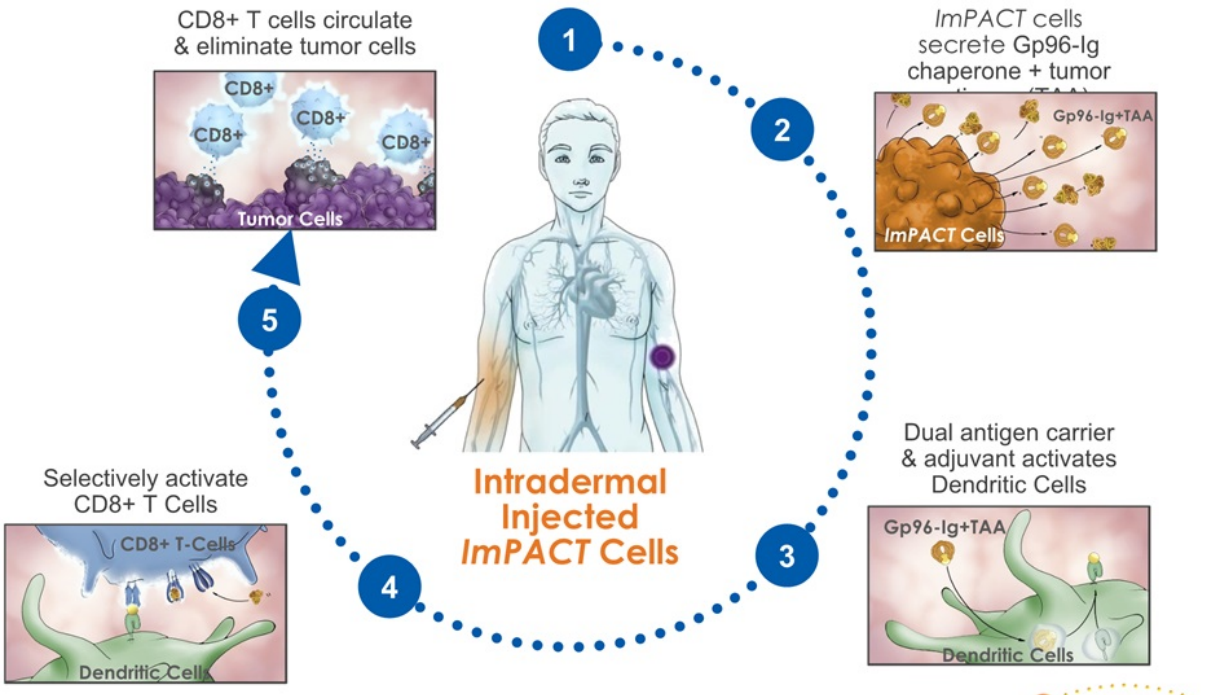
Addressing Three Distinct But Synergistic Mechanisms of Action to Optimize Cancer Immunotherapy



Overcome tumor defenses through combination therapies

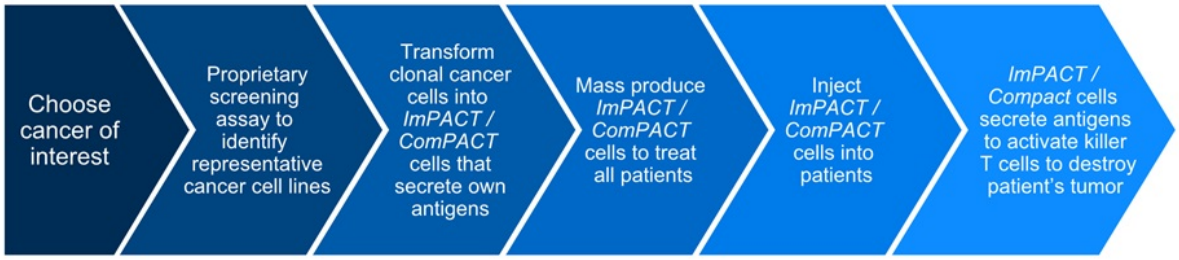
Heat Biologics

ImPACT



Heat Biologics

Drug Development and Manufacturing



Highlights

- Ready-to-use / Off-the-shelf product
- No tumors extracted
- Scalable manufacturing
- Lower cost of production than autologous cell therapies
- Established regulatory path

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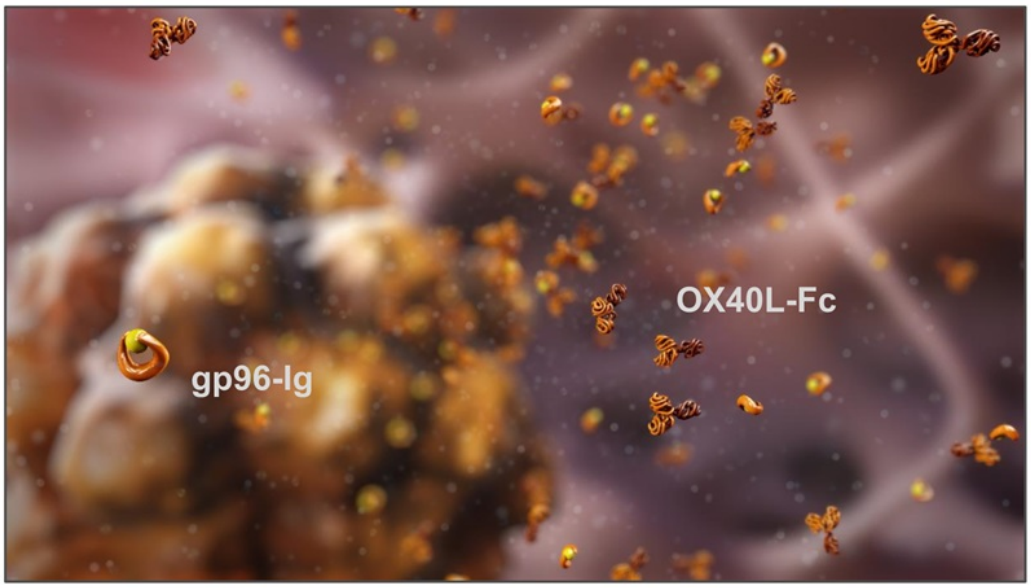
ComPACT



The first potential dual-acting immunotherapy designed to deliver T cell activation and costimulation in a single product

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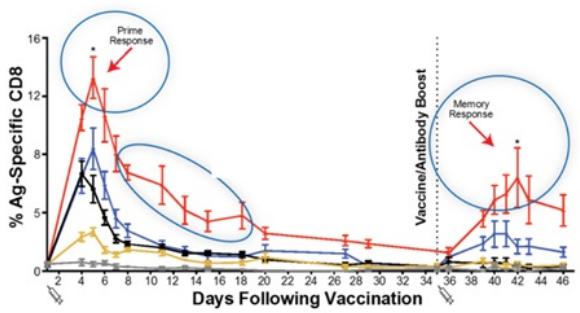
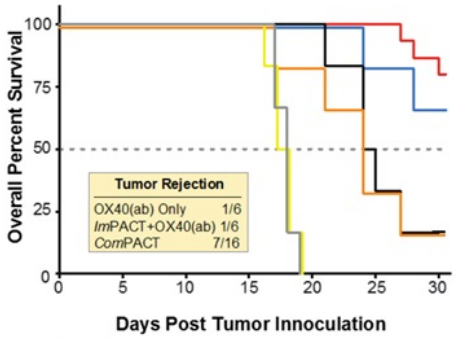
ComPACT Outperforms OX40 Monoclonal Antibodies in Preclinical Models





Untreated (N=6)
CT26 Only Control (N=6)
OX40(ab) Only (N=6)
*Im*PACT (N=6)
*Im*PACT + OX40(ab) (N=6)
*Com*PACT (N=6)

- *ComPACT* leads to approx. 50 percent complete tumor rejection as compared to approx. 16 percent with OX40 agonist antibody combinations
- Heat expects to announce its selection of the first product candidate based on *ComPACT* in the first quarter of 2016

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Pipeline

ImPACT

Product	Combination	Indication	Preclinical	Mfg	Phase 1	Phase 2	Phase 3
HS-410 (vesigenurtacel-L)	monotherapy; BCG	NMIBC	Randomized arms enrollment completed				
HS-110 (viagenpumatucel-L)	Nivolumab and other checkpoint inhibitors	NSCLC	Enrolling				
HS-110 (viagenpumatucel-L)	cyclophosphamide	NSCLC	Completed enrollment				

ComPACT

HS-X20	TBD	Undisclosed					

Heat Biologics

Pipeline

ImPACT

Product	Combination	Indication	Preclinical	Mfg	Phase 1	Phase 2	Phase 3
HS-410 (vesigenurtacel-L)	**monotherapy; BCG**	**NMIBC**	**Randomized arms enrollment completed**				
HS-110 (viagenpumatucel-L)	Nivolumab and other checkpoint inhibitors	NSCLC	Enrolling				
HS-110 (viagenpumatucel-L)	cyclophosphamide	NSCLC	Completed enrollment				

ComPACT

HS-X20	TBD	Undisclosed	

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

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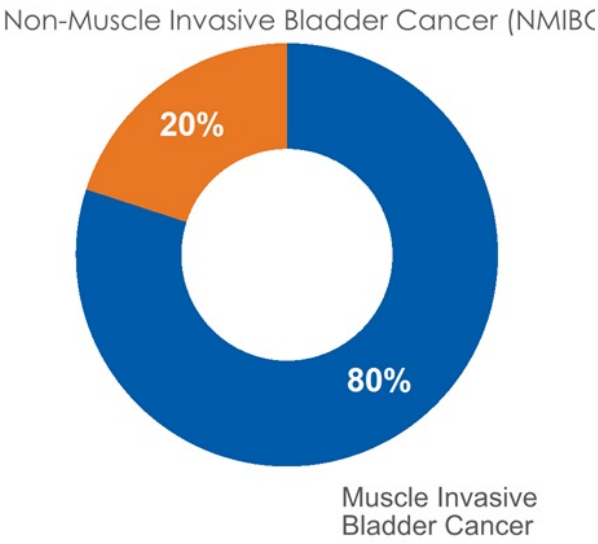
Bladder Cancer – NMIBC Opportunity

- Over 500,000 bladder cancer patients in U.S.[1]
- 73,000+ new cases and 15,000 deaths per year in U.S.[1]
- No new NMIBC treatments in 25 years
- Current standard of care is BCG[2]
- Highest lifetime treatment cost per patient of all cancers
  - Over $4 billion per year in U.S.[3]

Bladder Cancer



1. American Cancer Society 2012 Statistics; 2. BCG is Bacillus Calmette-Guérin; 3. NCI-PDQ, NCI costs of cancer care

Heat Biologics

HS-410 Phase 1 NMIBC Trial Overview

Design

- Open-label, multicenter safety trial; 10 patients enrolled
- Patients received BCG for 3-6 weeks followed by weekly intradermal injections of HS-410 for 12 weeks and subsequent monthly HS-410 injections for 3 months

Results

- HS-410 had a positive safety profile and was well-tolerated; no serious adverse events or treatment discontinuations
- 7 out of 10 patients had no documented recurrences >1 year after standard of care surgery
- Unprecedented increase in intratumoral CD8+ T cells following vaccination
- Broad-based (polyclonal) expansion of patient T cells
- HS-410 shared 15 or more tumor antigens in common with those expressed on the patients' cancer cells
- Strong correlation between baseline characteristics of TILs by T cell receptor (TCR) sequencing and clinical outcome

Clinical and Immune Response

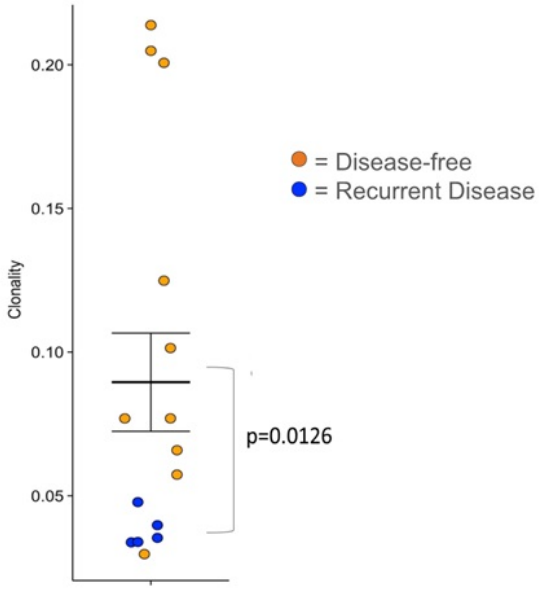
Disease Characteristics and Recurrence Status

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

Source: Heat's HS-410 Phase 1 NMIBC trial results presented at SITC 2015

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

Source: Heat's HS-410 Phase 1 NMIBC trial results presented at SITC 2015; TIL is tumor infiltrating lymphocyte

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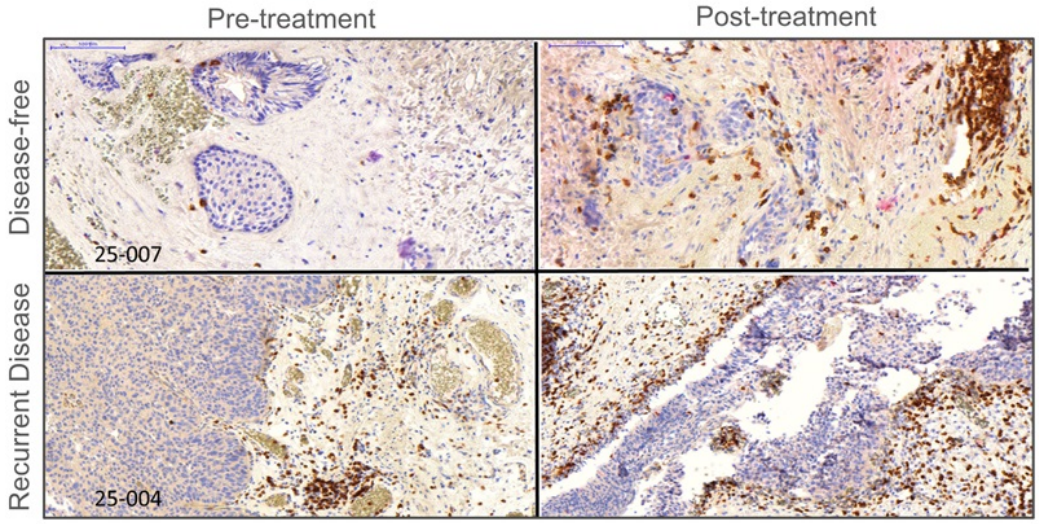
Post-treatment Induction of CD8+ TIL



- 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

Source: Heat's HS-410 Phase 1 NMIBC trial results presented at SITC 2015

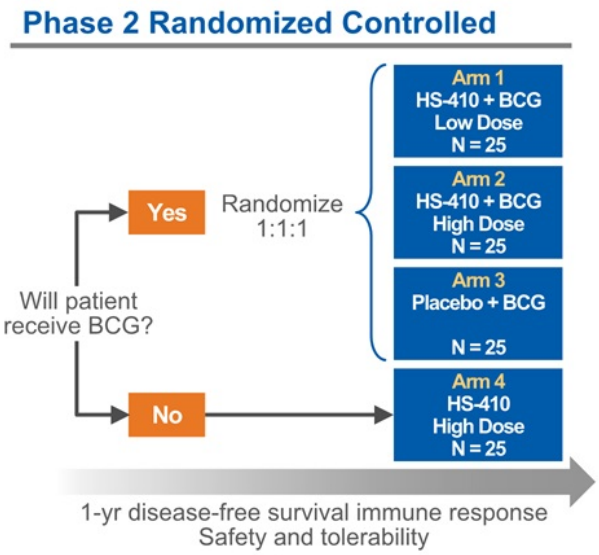
Heat Biologics

HS-410 Phase 2 NMIBC Trial Overview

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

Patient Population
- 100 patients with NMIBC (Ta, T1, CIS) after TURBT

Enrollment
- 16 U.S. sites
- Completed enrollment of 75 randomized patients; enrolling 25 patients in monotherapy arm[1]



Topline data expected 4Q:16

1. *As previously reported, Heat expects to complete enrollment for the monotherapy arm in late 2015/early 2016*

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Pipeline

ImPACT

Product	Combination	Indication	Preclinical	Mfg	Phase 1	Phase 2	Phase 3
HS-410 (vesigenurtacel-L)	monotherapy; BCG	NMIBC	Randomized arms enrollment completed				
HS-110 (viagenpumatucel-L)	**Nivolumab and other checkpoint inhibitors**	**NSCLC**	**Enrolling**				
HS-110 (viagenpumatucel-L)	**cyclophosphamide**	**NSCLC**	**Completed enrollment**				

ComPACT

HS-X20	TBD	Undisclosed					

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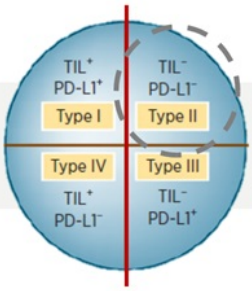
NSCLC Opportunity

CD8+ (TIL+) patients may respond to anti-PD-(L)1



CD8- (TIL-) patients may not respond to anti-PD-(L)1

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

1. National Cancer Institute 2013 statistics; Graphic source: Teng et al., 2015 Can Res; Gettinger et al., 2015 JCO

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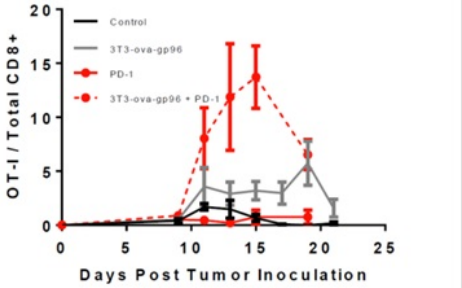
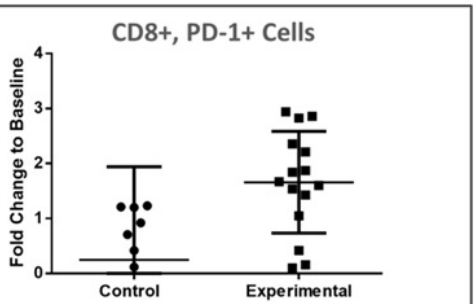
Scientific Support for HS-110 + Nivolumab Combination

1



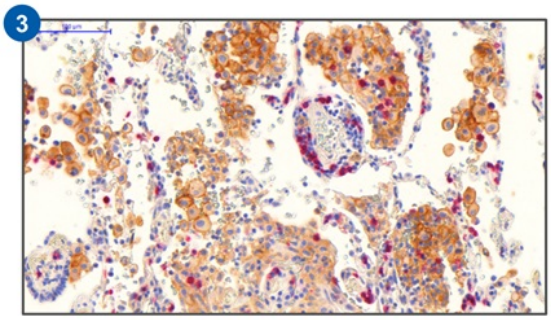
Schreiber T.H., et al. *Keystone 2014*

2



Cohen, R.B. et al. *ASCO 2015*

3



Tumor biopsy from patient treated with HS-110

1. Preclinical studies demonstrate synergy between *ImPACT* vaccines + anti-PD-1
2. Clinical data demonstrate that HS-110 treated patients upregulate PD-1 on CD8+ T cells
3. Tumor biopsies show strong PD-L1 staining

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HS-110 Phase 1b NSCLC "DURGA" Trial Overview

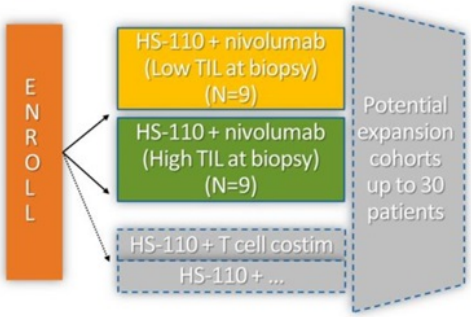
Objective
- Evaluate safety and tolerability of HS-110 + a PD-1 checkpoint inhibitor

Patient Population
- Potential to expand cohorts up to 30 patients

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

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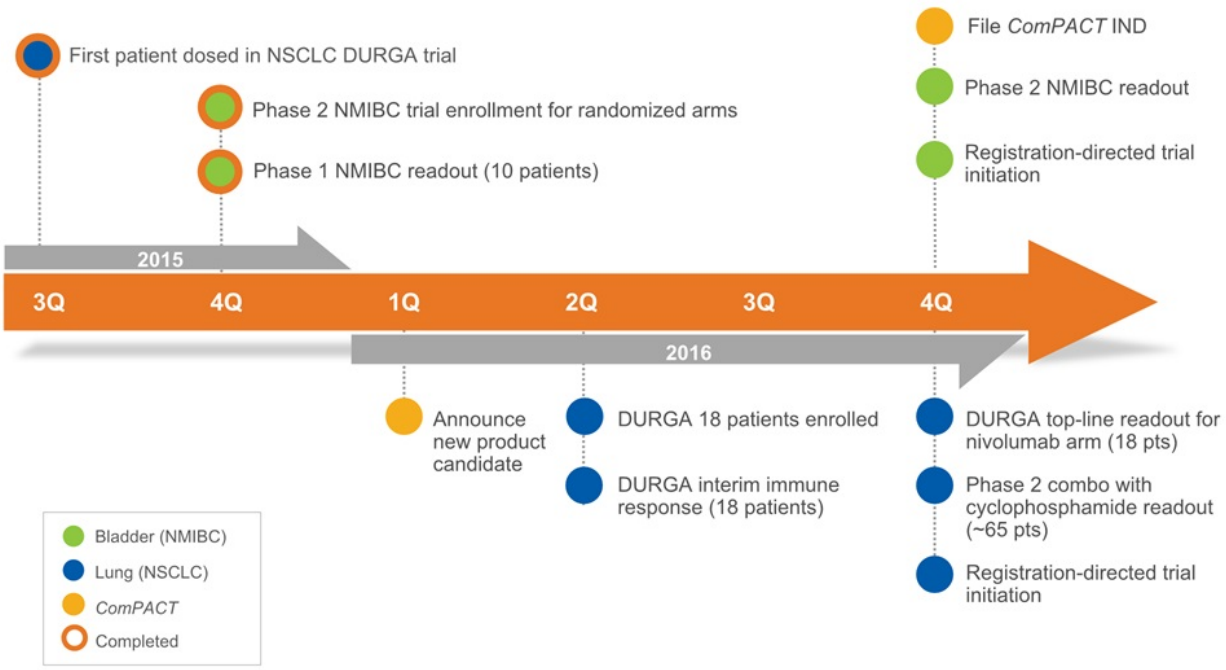
Development Milestones



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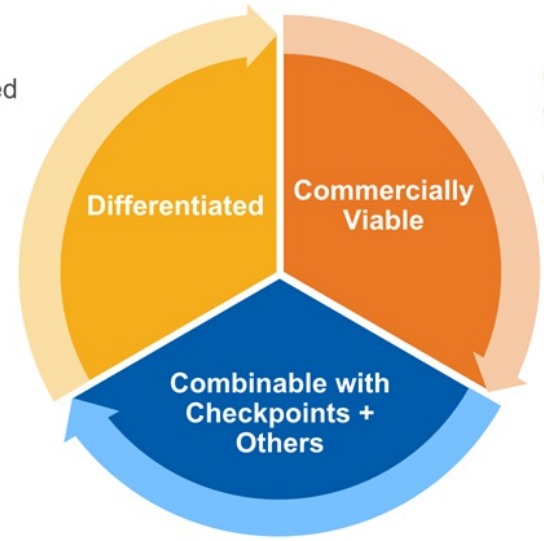
Summary: Value Proposition

- Pan-antigen cell-based
- Specific tumor killing T cell activating
- Applicable to all cancers



- Ready-to-use
- Scalable, low cost manufacturing
- No tumors extracted

- Positive safety profile to date
- Established regulatory path

Heat Biologics

Corporate Overview

Nasdaq	HTBX
Shares Outstanding	8.41M
Market Cap	$37.9M
Cash & Equiv.	$15.0 M[1]
Consensus Price Target	$15.5

1. As reported for the nine months ended September 30, 2015

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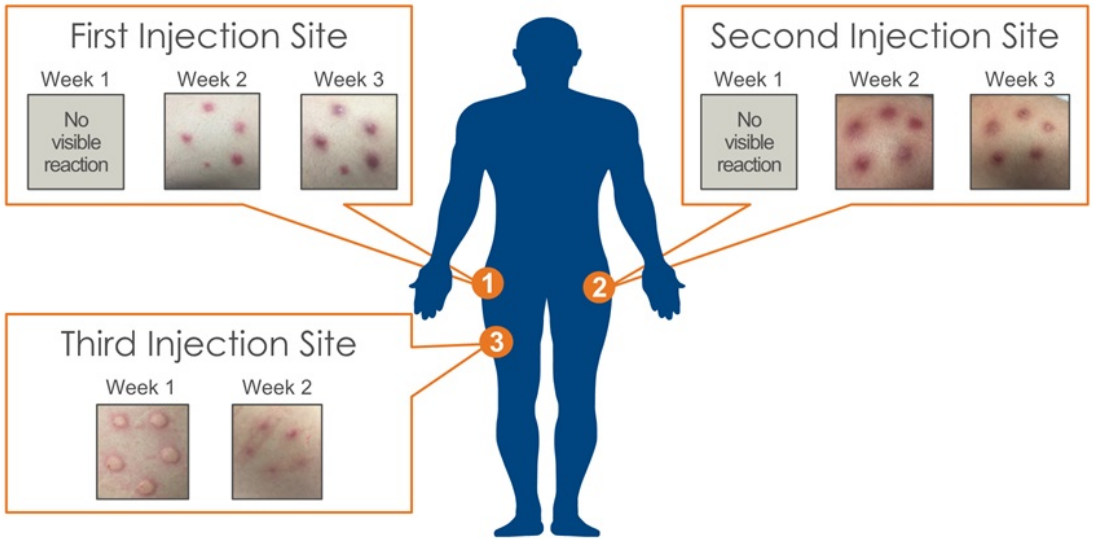
APPENDIX

HS-410 Injection Site Reactions

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



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High Degree of Overlap with Patient Tumor Antigens

Antigen	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

HS-410 shared 15 or more tumor antigens in common with those expressed on the patients' cancer cells

Source: Heat's HS-410 Phase 1 NMIBC trial results presented at SITC 2015

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THANK YOU