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 5, 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.)*

627 Davis Drive
Morrisville, NC 27560
(Address of principal executive offices and zip code)

(919) 240-7133
(Registrant's telephone number including area code)

801 Capitola Drive, Durham, NC 27713
(Former Name and Former Address, if Changed Since Last Report)

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))

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On November 5, 2019, an abstract (the "Abstract") titled "Treating Advanced Non-Small Lung Cancer Patients after Checkpoint Inhibitor Treatment Failure with a Novel Combination of Viagenpumatucel-L (HS-110) plus Nivolumab" which had been submitted by Heat Biologics, Inc. (the "Company") to The Society for Immunotherapy of Cancer's (SITC) in connection with its 34th Annual Meeting was published by SITC. The data presented was obtained from the Company's ongoing phase 2 study of previously-treated non-small lung cancer patients (NSCLC) of HS-110 in combination with nivolumab (Cohort B). Patients in this cohort have progressed after ≥ 4 months of prior treatment with a checkpoint inhibitor. The study evaluates whether the addition of HS-110 to nivolumab may restore responsiveness to treatment after tumor progression on prior checkpoint inhibitor therapy. Cohort B data presented below is based on 56 patients in the intent-to-treat (ITT) population at the time of data cut-off:

- Response rate by RECIST 1.1
  - Partial response (PR) in 7 patients (13%)
  - Stable disease (SD) in 26 patients (46%)
  - Disease control rate (DCR) was (59%)
- Median overall survival (OS) was estimated at 11.8 months (95% CI; 6.6 - not reached months) with 39 of the 56 patients censored (70% of patients still alive).
- Median progression free survival (mPFS) was estimated at 3.2 months (95% CI; 1.9 - 4.0 months) with 17 patients censored.
- Subset analysis based on Injection Site Reaction (ISR):
  - Patients who experienced an ISR versus those who did not experience ISR:
    - Improved PFS (3.7 vs 1.8 months; HR 0.40, *p =0.0068*)
    - Improved OS (12 vs 5 months; HR 0.16, *p=0.0005*)
- Combination of HS-110 and nivolumab was well tolerated by patients.
  - 92% of adverse events (AEs) were mild (Grade 1 or 2).
  - There were only four grade 4 events, and no grade 5 AEs.

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

The furnishing of the attached Abstract is not an admission as to the materiality of any information therein. The information contained in the Abstract is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

Item 8.01 Other Events.

On November 5, 2019, the Company issued a press release announcing that on November 5, 2019 an abstract titled"Treating Advanced Non-Small Lung Cancer Patients after Checkpoint Inhibitor Treatment Failure with a Novel Combination of Viagenpumatucel-L (HS-110) plus Nivolumab" which had been submitted by the Company to The Society for Immunotherapy of Cancer's (SITC) in connection with its 34th Annual Meeting was published by SITC. A copy of the press release regarding the Abstract is attached as Exhibit 99.2 and incorporated herein by reference.

A copy of the Company's new corporate slide presentation that includes information from the Abstract and data from the Company's ongoing phase 2 study is also attached to this Current Report on Form 8-K as Exhibit 99.3 and is incorporated herein by reference.

The Company undertakes no duty or obligation to update or revise information included in this Current Report or the Exhibits.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit Number	Description
99.1	Abstract titled "Treating Advanced Non-Small Lung Cancer Patients after Checkpoint Inhibitor Treatment Failure with a Novel Combination of Viagenpumatucel-L (HS-110) plus Nivolumab"
99.2	Press Release of Heat Biologics, Inc. dated November 5, 2018
99.3	Corporate Presentation dated November 2019

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 5, 2019

HEAT BIOLOGICS, INC.

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

EXHIBIT 99.1

Treating advanced non-small lung cancer (NSCLC) patients after checkpoint inhibitor treatment failure with a novel combination of Viagenpumatucel-L (HS-110) plus nivolumab

Daniel Morgensztern[1], Saiama N. Waqar[1], Lyudmila Bazhenova[2], Rachel E. Sanborn[3], Lori McDermott[4], Jeff Hutchins[4], Luis E. Raez[5], Corey J. Langer[6], Roger B. Cohen[6]

[1]Washington University School of Medicine, St. Louis, MO; [2]UC San Diego, Moores Cancer Center, La Jolla, CA; [3]Earle A. Chiles Research Institute, Providence Cancer Institute, Portland, OR; [4]Heat Biologics, Inc, Durham, NC; [5]Memorial Cancer Institute, Pembroke Pines, FL; [6]University of Pennsylvania Perelman School of Medicine, Philadelphia, PA

Background:
Viagenpumatucel-L (HS-110) is an allogeneic cellular vaccine derived from a human lung adenocarcinoma cell line transfected with the gp96-Ig fusion protein that functions as an antigen chaperone for cross presentation and dendritic cell activation. DURGA is a multi-cohort study evaluating the combination of HS-110 and anti-PD-1 monoclonal antibodies in patients with advanced NSCLC. We report on Cohort B, which enrolled patients with progressive disease (PD) after receiving a minimum of 4 months of treatment with a checkpoint inhibitor (CPI) at any time prior to study entry.

Methods:
Patients with previously treated NSCLC received weekly HS-110 (1 X 10^7 cells) intradermally for 18 consecutive weeks and nivolumab IV 240 mg every 2 weeks, followed by nivolumab maintenance until tumor progression or intolerable toxicity. Tissue was tested at baseline for PD-L1 expression ($\geq$ 1% or < 1%) and tumor infiltrating lymphocytes (TILs). TIL high was defined as >10% CD8+ lymphocytes in the tumor stroma. The primary endpoint was objective response rate (ORR) by RECIST 1.1. Secondary endpoints included ORR and clinical benefit rate using iRECIST, progression-free survival (PFS), overall survival (OS) and adverse events (AEs).

Results:
As of March 2019, 56 patients were enrolled and evaluated for efficacy. The median number of prior treatment lines was 2 [range 1 to 6]. Seven patients (13%) achieved partial response and 26 patients (46%) had stable disease. Median PFS and median OS were 3.2 months and 11.8 months, respectively. Immune ORR and clinical benefit rate by iRECIST were 14% and 61%, respectively. Patients experiencing injection site reactions (ISR) had improved PFS (3.7 vs 1.8 months; HR 0.21, *p =0.0021*) and improved OS (12 vs 5 months; HR 0.16, *p=0.0005*) compared to those without ISR. 96% of patients experienced at least one adverse event, and 92% of all AEs were grade 1 or 2. The most common AEs were fatigue (34%), hypocalcemia (18%), cough (16%) and diarrhea and dyspnea (14% each). There were four grade 4 events: QTc prolongation, stroke, pericardial tamponade, and hyponatremia, none of which were deemed related to treatment. There were no grade 5 AEs.

Conclusions:

The combination of HS-110 and nivolumab is well tolerated, and does not appear to increase the incidence of immune-related AEs as compared to CPI monotherapy. Patients continue to be enrolled into this cohort. Data suggest that re-challenging the immune system with nivolumab and HS-110 after CPI treatment failure restores responsiveness and clinical benefit for some patients.

EXHIBIT 99.2

Heat Biologics Reports Positive Phase 2 Interim Data in NSCLC Patients Who Previously Failed Checkpoint Inhibitor Treatment

Announces Abstract Summarizing Favorable
Interim Phase 2 Data of HS-110 Plus Nivolumab

Additional Data to be Reported in Poster Presentation
at the SITC 34th Annual Meeting on November 8, 2019

DURHAM, NC – November 5, 2019 – Heat Biologics, Inc. (NASDAQ: HTBX), a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer, today announced that an abstract has been posted on The Society for Immunotherapy of Cancer's (SITC) website in connection with the Company's planned poster presentation at SITC's 34th Annual Meeting on November 8, 2019.

The abstract summarizes the latest interim top line data from Cohort B of the Company's Phase 2 trial of the Company's "off-the-shelf" cell-based therapy, HS-110, in combination with Opdivo® (Nivolumab) in advanced non-small cell lung cancer (NSCLC), which completed enrollment in July 2019. This cohort enrolled patients who had previously received a checkpoint inhibitor (CPI) and whose disease had subsequently progressed. The data suggests that re-challenging the immune system with nivolumab and HS-110 after checkpoint inhibitor treatment failure may restore responsiveness and clinical benefit. Additionally, the combination of HS-110 and nivolumab is well-tolerated, and no increase in the incidence of immune-related adverse events was observed to date, as compared to CPI monotherapy. The full abstract is available at: https://www.heatbio.com/technology/scientific-publications

Jeff Wolf, Heat Biologics' CEO, commented, "NSCLC patients who progressed after checkpoint inhibitor treatment have limited therapeutic options. The latest results are encouraging and suggest that HS-110 in combination with nivolumab may address this key unmet medical need. As of this data cut, the median overall survival (OS) is estimated to be 11.8 months, with 70% of the patients still alive. I am unaware of any published checkpoint combination studies that offered superior OS in patients that had experienced previous checkpoint inhibitor treatment failure in NSCLC. This data also compares favorably to reported studies using chemotherapy following checkpoint inhibitor progression [1, 2] ".

Signals of clinical efficacy were observed in the reported objective response rate (ORR), disease control rate (DCR) and progression free survival (PFS). Importantly, patients experiencing dermal injection site reactions (ISR) had statistically significant improvement in PFS and OS compared to those without ISR (Hazard Ratio = 0.40, p=0.0068 and Hazard Ratio = 0.16, p=0.0005, respectively). Additional data will be presented at SITC on November 8 ,2019.

Details of Heat Biologics' poster presentation:

Abstract Title: Treating advanced non-small lung cancer (NSCLC) patients after checkpoint inhibitor treatment failure with a novel combination of Viagenpumatucel-L (HS-110) plus nivolumab

Poster #: P411

Date: Friday, November 8, 2019, 7am – 8pm (Eastern Time)

Location: Gaylord National Hotel & Convention Center, Washington DC

References:

[1] Costantini A, Corny J, Fallet V et al. Efficacy of next treatment received after nivolumab progression in patients with advanced nonsmall cell lung cancer. ERJ Open Res. 2018 Apr 20;4(2).

[2] Schvartsman G, Peng SA, Bis G, et al. Response rates to single-agent chemotherapy after exposure to immune checkpoint inhibitors in advanced non-small cell lung cancer. Lung Cancer. 2017 Oct;112:90-95.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using CD8+ "Killer" T-cells. HS-110 is the Company's first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Heat has completed enrollment in its Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®) or with Merck's pembrolizumab (Keytruda®). Pelican Therapeutics, a subsidiary of Heat, is focused on the development of co-stimulatory monoclonal antibody and fusion protein-based therapies designed to activate the immune system. Heat also has numerous pre-clinical programs at various stages of development. 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 on our current expectations and projections about future events. In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “potential,” “continue,” “expects,” “anticipates,” “intends,” “plans,” “believes,” “estimates,” and similar expressions. These statements are based upon current beliefs, expectations and assumptions and include statements such as: the data suggests that re-challenging the immune system with nivolumab and HS-110 after checkpoint inhibitor treatment failure may restore responsiveness and clinical benefit and these latest results suggests that HS-110 in combination with nivolumab may address a key unmet medical need for NSCLC patients . These statements are based on management’s expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements, including the ability of Heat’s therapies to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, Heat’s ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Heat’s ability to promote or commercialize its product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products, Heat’s ability to maintain its license agreements, the continued maintenance and growth of its patent estate, its ability to establish and maintain collaborations, its ability to obtain or maintain the capital or grants necessary to fund its research and development activities, its ability to retain its key scientists or management personnel, and the other factors described in Heat’s Annual Report on Form 10-K and 10-K/A for the year ended December 31, 2018 and other subsequent filings with the SEC. The information in this release is provided only as of the date of this release and the company undertakes no obligation to update any forward-looking statements contained in this release based on new information, future events, or otherwise, except as required by law

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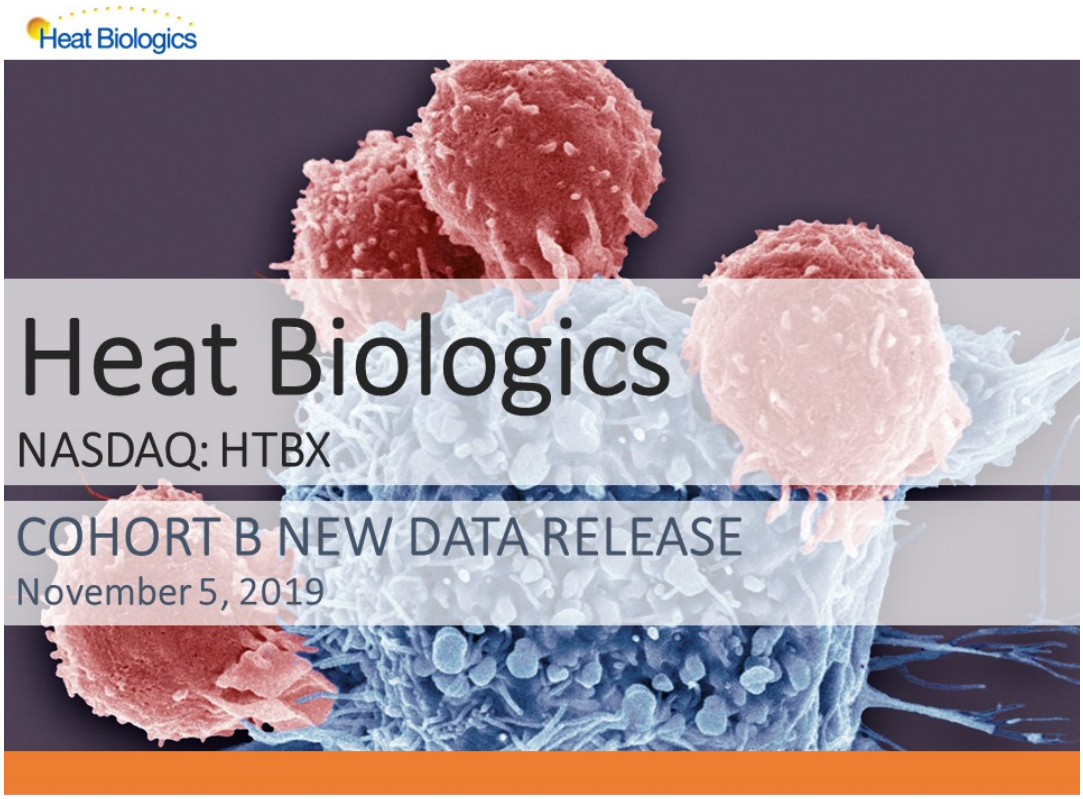

Heat Biologics
Heat Biologics
NASDAQ: HTBX
COHORT B NEW DATA RELEASE
November 5, 2019

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.

Executive Summary

- HS-110, an "off the shelf" cell-based immunotherapy product that has the potential to improve PD(L)-1 based therapy
  - Broad market potential in multiple oncology indications
  - Fully allogeneic product with low COGs
- Ongoing Phase 2 program demonstrates signals of efficacy in two treatment settings
- Latest data for Cohort B presented here evaluated combination of HS-110 and nivolumab in checkpoint inhibitor progressor non-small cell lung cancer (NSCLC) patients
  - A subset of the HS110-102 trial
  - All patients had progressive disease (PD) after receiving a minimum of 4 months of checkpoint inhibitor (CPI) therapy at any time prior to study entry
    - Recruitment for this cohort closed in June 2019
  - This data cut of July 2019 represents topline data from 56 patients who have been on study and followed for 18 weeks or greater

Heat Biologics

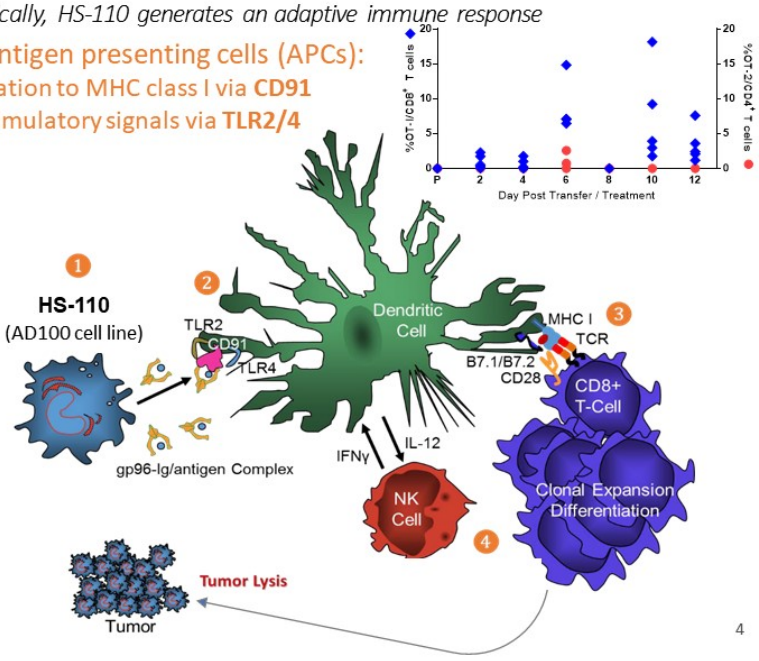
HS-110 Mechanism of Action

Pre-clinically, HS-110 generates an adaptive immune response

2 signals Delivered to antigen presenting cells (APCs):

- ✓ Antigen cross presentation to MHC class I via **CD91**
- ✓ Up regulation of co-stimulatory signals via **TLR2/4**

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



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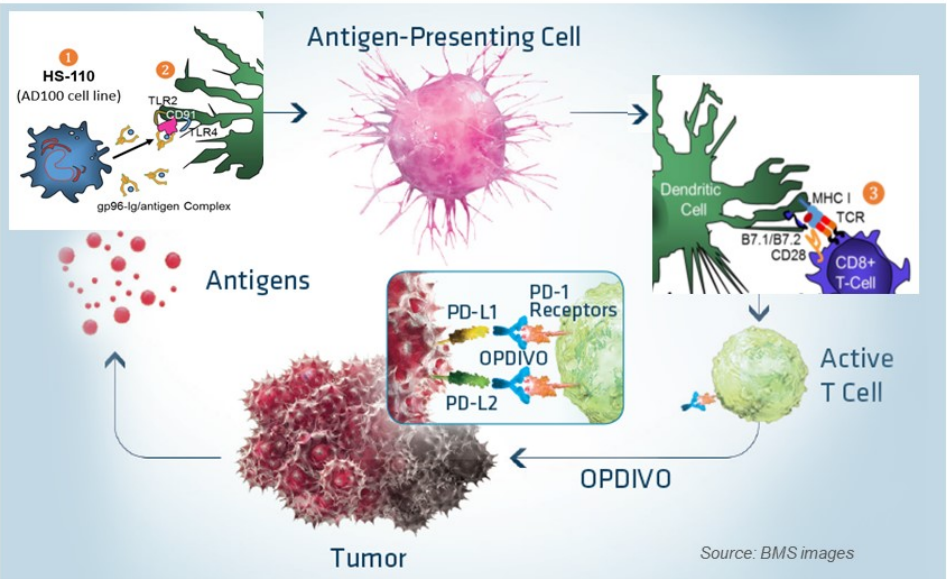
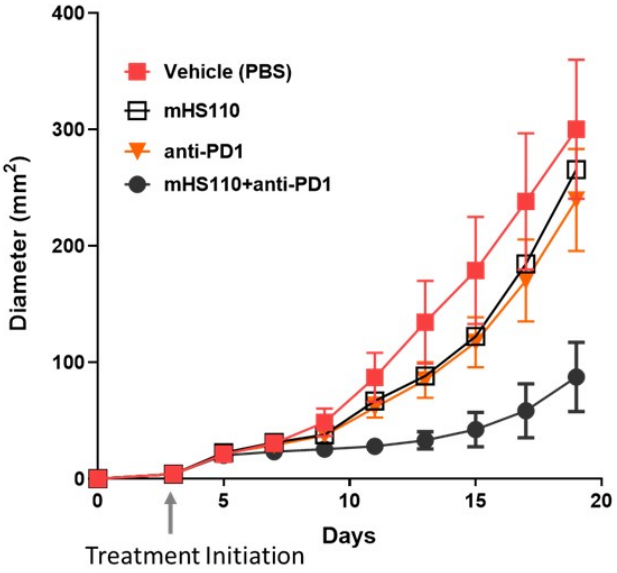
HS-110 + Opdivo Combination Therapy

Potential to improve clinical responses and survival, without additional toxicity



Synergistic Combination of HS-110 and PD-1 Inhibitor

in preclinical mouse tumor growth B16F10 model



- Pre-clinical data showed the synergistic anti-tumor-growth activity of mouse HS-110 with PD-1 inhibitor as compared to either agent individually, supporting further clinical evaluation

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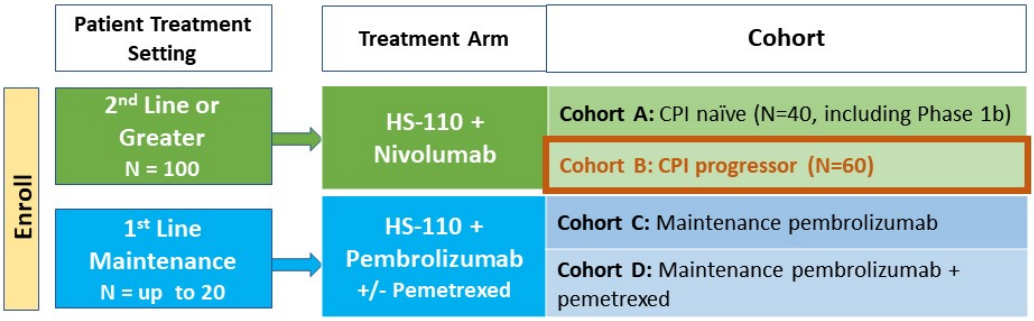
HS110-102 Trial Design

A Phase 1b/2 study of HS-110 in combination with multiple treatment regimens for patients with non-small cell lung cancer (HS110-102 trial, aka the "DURGA" Trial)



Primary Endpoints

Phase 1b:
Safety

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

Secondary Endpoints

OS, PFS, DCR, DOR

Exploratory Endpoints

Correlation of clinical outcomes to the following factors

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

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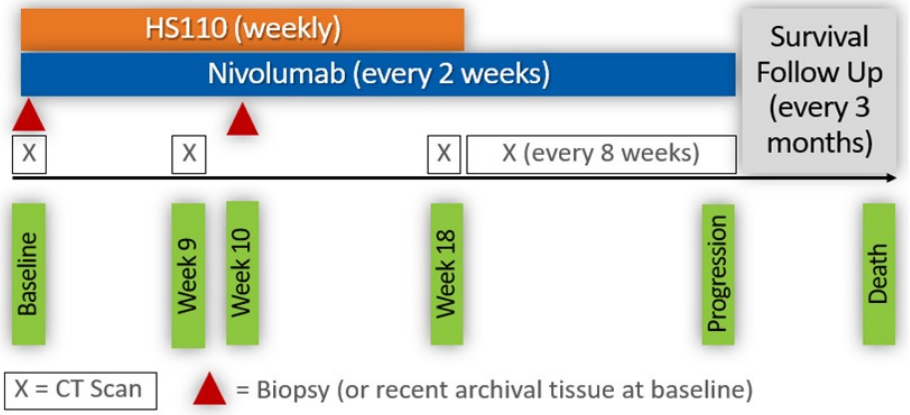
HS110-102 Trial Schema

A Phase 1b/2 study of HS-110 in combination with multiple treatment regimens for patients with non-small cell lung cancer (HS110-102 trial, aka the "DURGA" Trial)



Patients receive weekly HS-110 (1 x 10^7 cells) intradermally for 18 weeks via 5 simultaneous injections of 0.1ml each, and biweekly nivolumab 240 mg IV until disease progression or unacceptable toxicity.

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Cohort B: Patient Characteristics

Unresectable or metastatic NSCLC patients, heavily pretreated
(63% with ≥ 2 lines of prior therapy)

July 2019 data cut		ITT (N = 56)
Median age (range)		68 (50 – 84)
Female gender		30 (54%)
Caucasian		45 (80%)
ECOG PS 1		36 (64%)
Driver Mutation	EGFR + ALK + KRAS +	2 (4%) 1 (2%) 14 (25%)
Histology	Adeno Squamous Other	45 (80%) 10 (18%) 1 (2%)
Smoking Status	Current/past Never	48 (86%) 8 (14%)
Prior lines of Treatment	1 2 ≥ 3	21 (37%) 16 (29%) 19 (34%)

July 2019 data cut		ITT (N = 56)
Baseline PD-L1	Negative (< 1%) Positive (≥ 1%) Unevaluable	22 (39%) 20 (36%) 14 (25%)
Baseline CD8+ TIL	Low (≤ 10%) High (> 10%) Unevaluable	14 (25%) 18 (32%) 24 (43%)
Time on prior CPI: Median (range), months		10 (3 – 58)
Time between last CPI dose and study entry: Median (range), months		2 (1 – 35)

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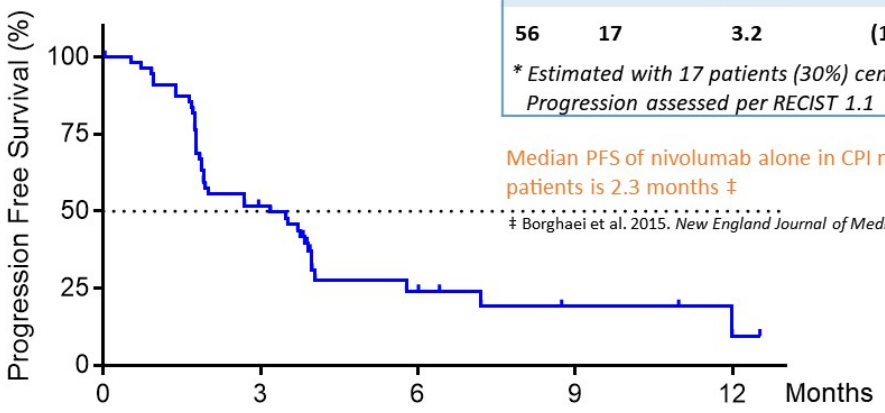
Cohort B:

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

Estimated Progression Free Survival (PFS)

ITT	Censored	Median PFS * (months)	95% CI
56	17	3.2	(1.9, 4.0)

** Estimated with 17 patients (30%) censored. Progression assessed per RECIST 1.1*



Number at risk	56	27	8	4	2

Median PFS of nivolumab alone in CPI naïve patients is 2.3 months ‡

‡ Borghaei et al. 2015. *New England Journal of Medicine*

July 2019 data cut

Heat Biologics

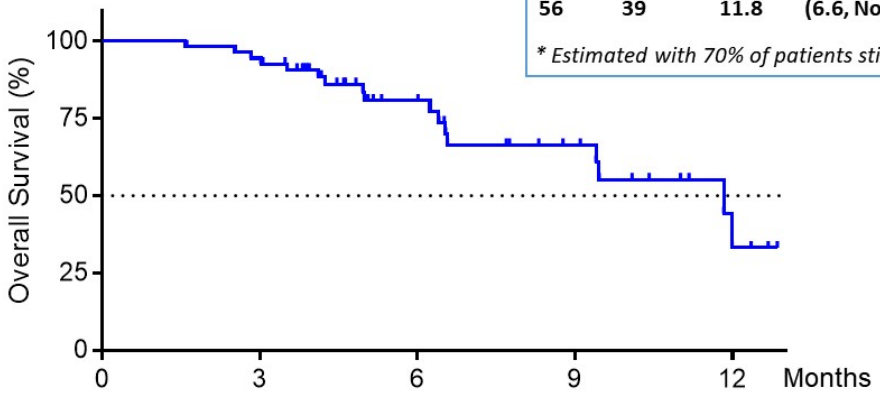
Cohort B:

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

Estimated Median Overall Survival (OS)

ITT	Censored	Median OS*, 95% CI (mos)	
56	39	11.8	(6.6, Not Reached)

** Estimated with 70% of patients still alive*



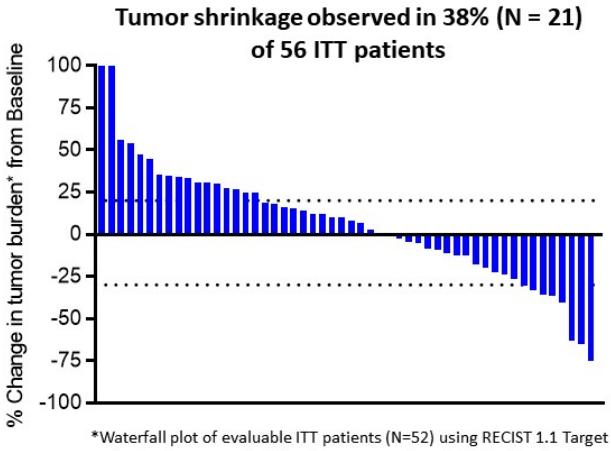
Number at risk	56	52	27	14	4

July 2019 data cut

Heat Biologics

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

Objective Response Rate (ORR)



*Waterfall plot of evaluable ITT patients (N=52) using RECIST 1.1 Target Lesion Response. Post-baseline scans not available for 4 patients.

ITT population (N=56)

	iRECIST †	RECIST 1.1 †
ORR	**14% (8)**	**13% (7)**
PR	14% (8)	13% (7)
SD	46% (26)	46% (26)
Not Evaluable	7% (4)	7% (4)
DCR	**61% (34)**	**59% (33)**

† unconfirmed as study is actively ongoing at time of analyses. ORR performed locally by study Investigators using RECIST 1.1. Per iRECIST, one patient achieved confirmed PR after initial radiographic PD.

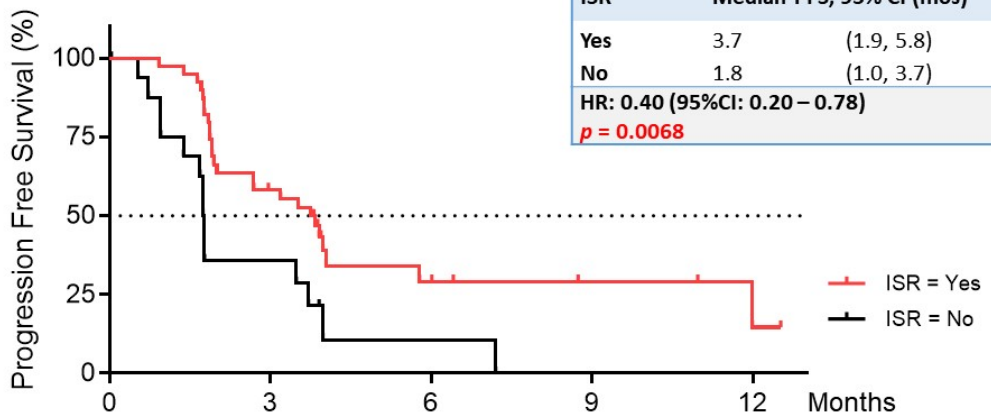
Heat Biologics

Cohort B:

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

PFS by Injection Site Reaction (ISR)

ISR	Median PFS, 95% CI (mos)	
Yes	3.7	(1.9, 5.8)
No	1.8	(1.0, 3.7)
HR: 0.40 (95%CI: 0.20 – 0.78)		
***p* = 0.0068**		



Number at risk	39	22	7	4	2
	17	7	2	1	1

ISR = Yes refers to patients who experienced at least one injection site reaction at any time during treatment (N = 39)

Heat Biologics

Cohort B:

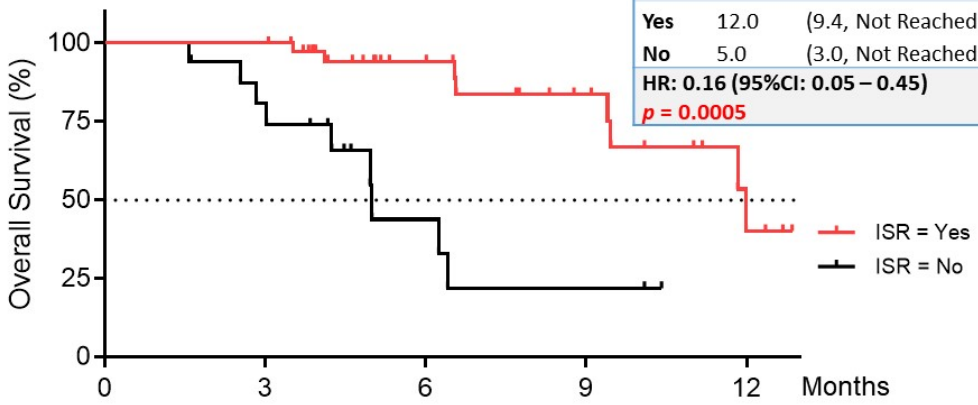
CPI progressors treated by HS-110 + Nivolumab at ≥2L

OS by Injection Site Reaction (ISR)

ISR	Median OS, 95% CI (mos)	
Yes	12.0	(9.4, Not Reached)
No	5.0	(3.0, Not Reached)

HR: 0.16 (95%CI: 0.05 – 0.45)

***p* = 0.0005**



Number at risk	39	39	23	12	4
	17	13	5	3	1

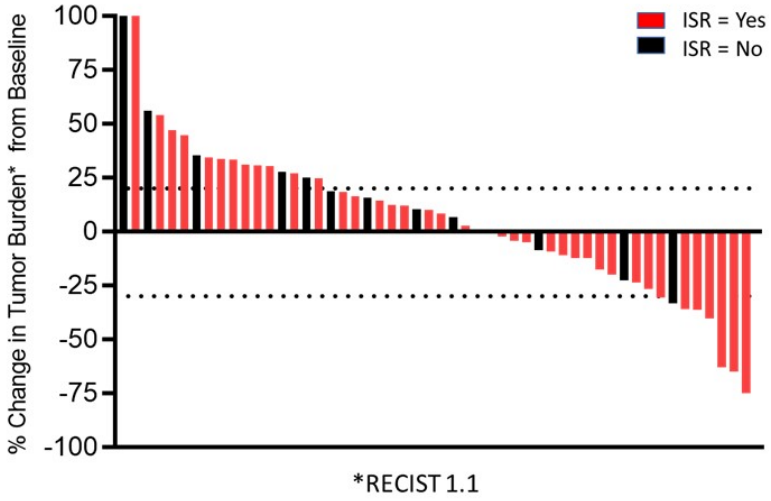
ISR = Yes refers to patients who experienced at least one injection site reaction at any time during treatment (N = 39)

Heat Biologics

Cohort B:

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

Best Target Lesion by ISR



July 2019 data cut

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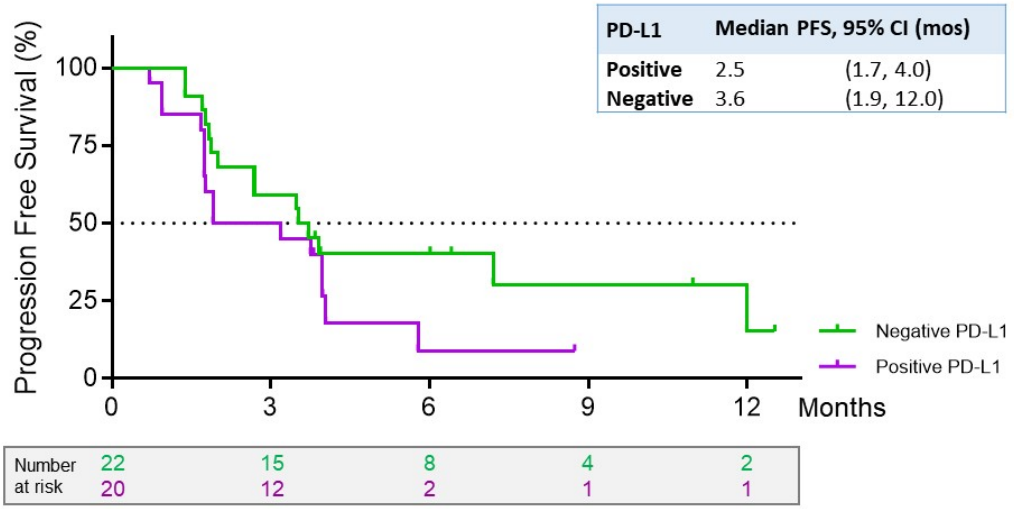
Cohort B:

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

PFS by Baseline PD-L1 Status

PD-L1	Median PFS, 95% CI (mos)	
Positive	2.5	(1.7, 4.0)
Negative	3.6	(1.9, 12.0)



Number at risk	22	15	8	4	2
	20	12	2	1	1

Negative PD-L1 is defined as <1%

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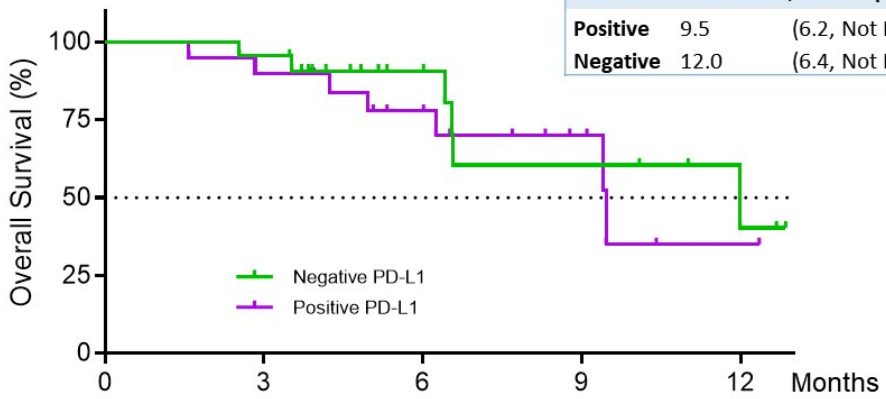
Cohort B:

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

OS by Baseline PD-L1 Status

PD-L1	Median OS, 95% CI (mos)	
Positive	9.5	(6.2, Not Reached)
Negative	12.0	(6.4, Not Reached)



Number at risk	22	22	11	7	3
	20	18	12	6	2

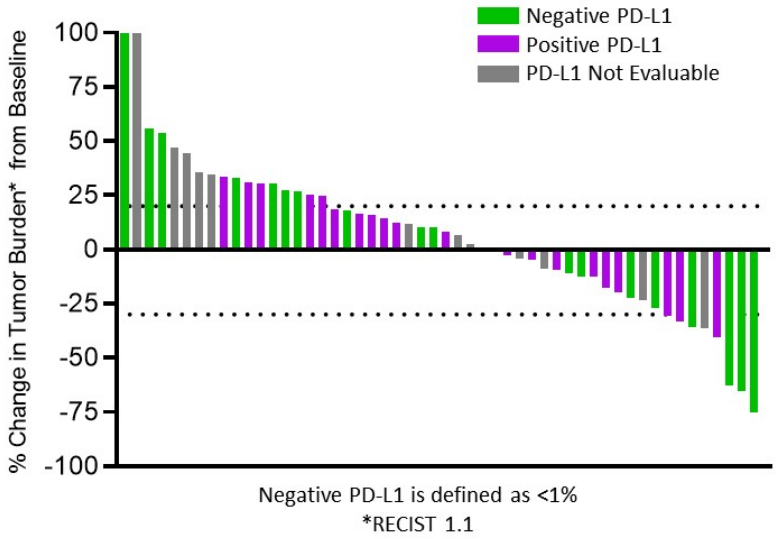
Negative PD-L1 is defined as <1%

Heat Biologics

Cohort B:

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

Best Target Lesion by Baseline PD-L1 Status



Negative PD-L1 is defined as <1%

*RECIST 1.1

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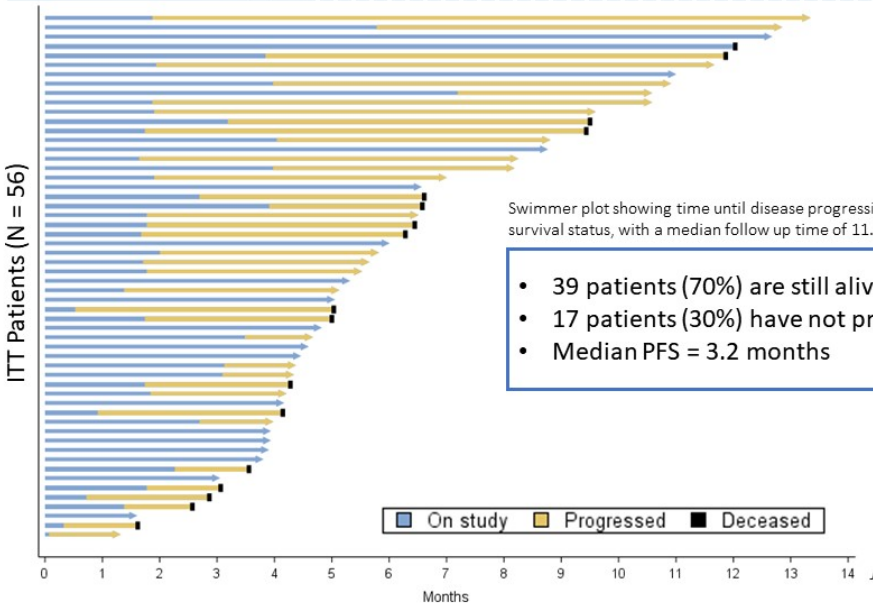
Cohort B:

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

Duration of Clinical Benefit



Swimmer plot showing time until disease progression and current survival status, with a median follow up time of 11.8 months

- 39 patients (70%) are still alive
- 17 patients (30%) have not progressed
- Median PFS = 3.2 months

July 2019 data cut

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

Comparison with Current Literature

A comparison with published literature in NSCLC patients *after PD-(L)1 progression*

	HS-110 + Nivolumab at ≥ 2nd line after CPI failure Δ	**Treatment Options** at ≥ 3rd line after CPI failure			
		Gemcitabine †	Docetaxel †	Erlotinib †	Single agent chemotherapy ‡
N	56	27	25	18	28
Median PFS (months)	3.2	2.8	2.7	2.0	4.7
Median OS (months)	11.8	7.5	6.8	2.7	9.0

Δ Heat Biologics Cohort B as of July 2019 data cut estimate with 70% of the patients still alive
† Constatini et al 2018 ERJ Open Research
‡ Schvartsman et al 2017 Lung Cancer

Cohort B:

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

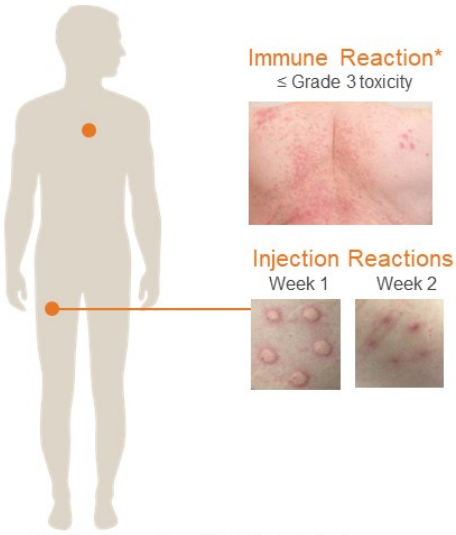
Key Data Summary

- Response rate by RECIST 1.1
  - Objective response rate (ORR) was 13%
  - Disease control rate (DCR) was 59%
- Median overall survival (OS) was estimated at 11.8 months with 70% of patients still alive
- Median progression free survival (mPFS) was 3.2 months
- Patients who experienced an ISR vs. those who did not:
  - Improved PFS (HR = 0.40, p = 0.0068)
  - Improved OS (HR = 0.16, p = 0.0005)
- The effect of HS-110 in combination with nivolumab is not dependent on PD-L1 expression
- Combination of HS-110 and nivolumab was well tolerated by patients

Favorable Safety Profile to Date

- Over 1,000 doses administered to 150+ patients
- Only one patient ended treatment due to an HS-110 related non-serious adverse reaction *
- No treatment-related serious adverse reactions
- No increase in immune-related adverse events compared to single-agent checkpoint inhibitors

No additive toxicities to standard of care



*Represents the only patient of 150+ patients dosed who discontinued treatment for a HS-110 related adverse event

Heat Biologics

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NASDAQ: HTBX

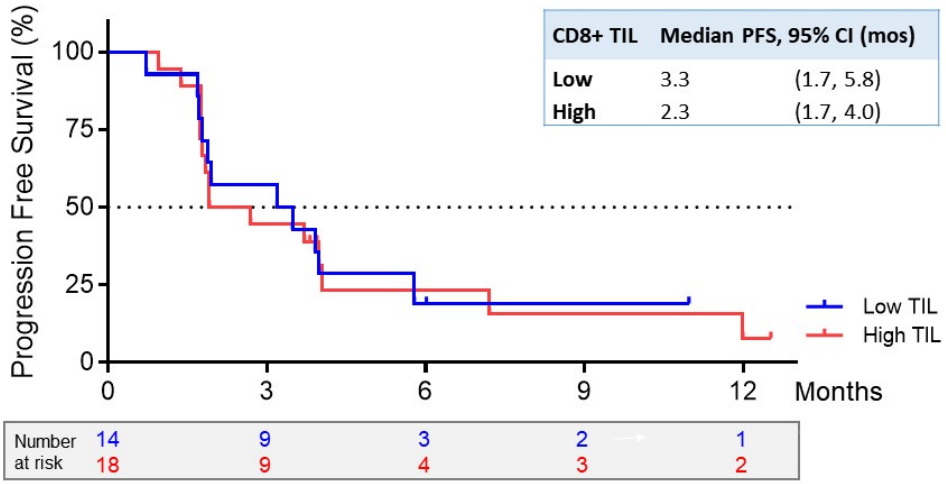
APPENDIX

Heat Biologics

Cohort B:

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

PFS by Baseline CD8+ TIL



CD8+ TIL	Median PFS, 95% CI (mos)	
Low	3.3	(1.7, 5.8)
High	2.3	(1.7, 4.0)

Number at risk					
Low TIL	14	9	3	2	1
High TIL	18	9	4	3	2

Low TIL is defined as CD8+ tumor infiltrating lymphocytes (TIL) ≤ 10%

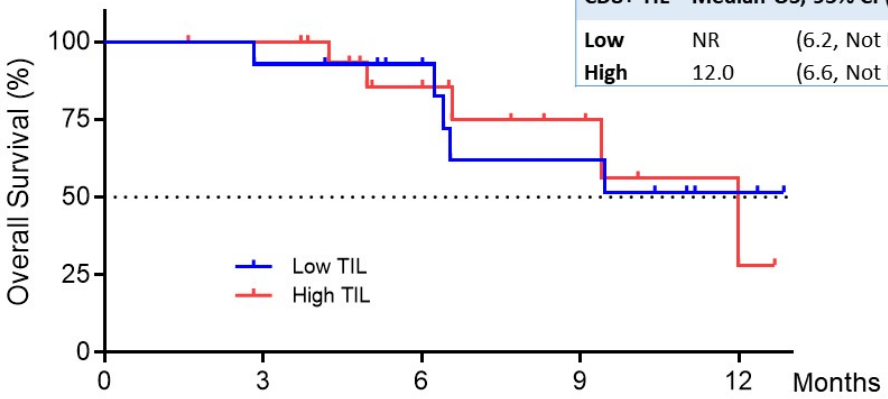
Heat Biologics

Cohort B:

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

OS by Baseline CD8+ TIL

CD8+ TIL	Median OS, 95% CI (mos)	
Low	NR	(6.2, Not Reached)
High	12.0	(6.6, Not Reached)



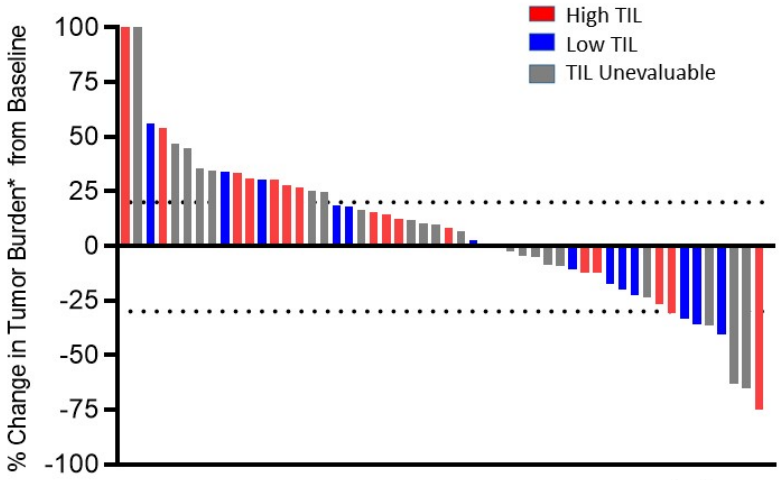
Number at risk					
	14	14	11	7	3
	18	18	11	6	2

Low TIL is defined as CD8+ tumor infiltrating lymphocytes (TIL) ≤ 10%

Cohort B:

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

Best Target Lesion by Baseline CD8+ TIL Status



Low TIL is defined as CD8+ tumor infiltrating lymphocytes (TIL) ≤ 10%

*RECIST 1.1

Cohort B:

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

Safety Summary

Most commonly reported treatment-emergent events (regardless of attribution) occurring in the safety population

Adverse Events (AEs)	ITT (N=56)
Any Adverse Event	54 (96%)
Any event ≥ Grade 3	13 (23%)
Fatigue	19 (34%)
Weight decreased	10 (18%)
Hypocalcemia	10 (18%)
Cough	9 (16%)
Diarrhea	8 (14%)
Dyspnea	8 (14%)

As of July 2019 data cut: 92% of all AEs were Grade 1 or 2. There were four grade 4 events, QTc prolongation, stroke, pericardial tamponade, and hyponatremia, none of which were deemed related to treatment. There were no grade 5 AEs.