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): **September 1, 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

On September 1, 2015, Heat Biologics, Inc. ("Heat"), issued a press release regarding dosing of its first patient in a Phase 1b clinical trial investigating the combination of its HS-110 therapeutic vaccine and the Bristol-Myers Squibb PD-1 inhibitor nivolumab in non-small cell lung cancer. A copy of the press release is attached as Exhibit 99.1. Heat will be hosting an investor conference call on Tuesday, September 1, 2015 to discuss the clinical trial. In connection therewith, Heat's management intends to discuss the slide presentation furnished as Exhibit 99.2 hereto, which is incorporated herein by reference.

The press release and slide presentation attached as Exhibits 99.1 and 99.2 to this Report include "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 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 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 exhibits are being filed as part of this Report.

Exhibit Number	Description
99.1	Press Release issued on September 1, 2015
99.2	Presentation materials to be provided at the Heat Biologics, Inc. investor conference call.

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: September 1, 2015

HEAT BIOLOGICS, INC.

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued on September 1, 2015
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EXHIBIT 99.1

Heat Biologics Announces Clinical Trial Combining HS-110 and PD-1 Checkpoint Inhibitor in NSCLC

Checkpoint Combination Trial to Replace Existing Trial in New Treatment Landscape; Timelines to Registration-Directed Study Remain Unchanged

Conference Call and Webcast Today at 8:30 AM EDT

DURHAM, NC – September 1, 2015 – Heat Biologics, Inc. (NASDAQ: HTBX), a clinical stage cancer immunotherapy company, announced that it has enrolled the first patient in a Phase 1b clinical trial investigating the combination of its HS-110 therapeutic vaccine and the Bristol-Myers Squibb PD-1 inhibitor nivolumab (Opdivo®) in non-small cell lung cancer (NSCLC). HS-110 is the Company's first product candidate in a series of proprietary *ImPACT*™ based immunotherapies designed to stimulate patient's own T-cells to attack cancer. Additionally, as the FDA approval of nivolumab and anticipated approval of other checkpoint inhibitors is dramatically changing the standard of care in lung cancer treatment, Heat is winding down its ongoing Phase 2 trial with HS-110, which does not include a checkpoint inhibitor combination, to instead focus on combinations with checkpoint inhibitors.

This multicenter trial is evaluating the safety and efficacy of HS-110 in combination with nivolumab in patients with NSCLC whose cancers have progressed after first-line therapy. Primary and secondary trial endpoints include safety and tolerability, immune response, overall response rate and progression-free survival.

"Checkpoint inhibitors such as nivolumab are rapidly becoming standard of care in the treatment of NSCLC and many other types of cancer," stated Jeff Wolf, CEO of Heat Biologics. "Substantial evidence is emerging regarding the benefits of combining checkpoint inhibitors and therapeutic vaccines. Heat had previously reported synergy between *ImPACT* and anti-PD-1 therapy. This important clinical study is among the first trials to explore the combination of a checkpoint inhibitor and therapeutic vaccine in NSCLC and will enable us to more fully evaluate this combination with other checkpoint inhibitors, such as Merck's pembrolizumab, as they become available."

"We reported earlier this year, in a clinical trial for HS-410 for bladder cancer, that patients with low levels of tumor-infiltrating lymphocytes (TILs) at baseline appeared to respond better," said Taylor Schreiber, M.D., Ph.D., Heat's Chief Scientific Officer. "This is consistent with emerging clinical evidence demonstrating that while responses to checkpoint inhibitor therapy are biased toward patients with pre-existing TILs, the optimal patient population for therapeutic vaccines in conjunction with checkpoint inhibitors may in fact be the checkpoint unresponsive (and TIL negative) population. Currently, only 20% to 30% of NSCLC patients respond to nivolumab. This trial will specifically investigate whether HS-110 can broaden the base of patients who respond to nivolumab and other checkpoint inhibitors."

“This trial is expected to initially enroll 18 patients, and is designed to accommodate rapid cohort expansion as positive clinical data emerge,” stated Melissa Price, Ph.D., Heat’s VP of Product Development. “We will be working with Yale Cancer Center’s Translational Immuno-Oncology Laboratory on the analysis of the TILs biomarker data for patient selection. We expect to release top-line objective response rate and 6-month progression free survival (PFS) data on these first 18 patients by the end of 2016, which should enable us to reach a clinical readout for HS-110 with a checkpoint-focused clinical trial, on the same schedule that we had forecasted for our previous trial. Our expectations around the timing of an HS-110 registration-directed study in NSCLC remain unchanged.”

Nivolumab (Opdivo) was approved by the US Food and Drug Administration (FDA) for the treatment of NSCLC in March 2015 and is marketed by Bristol-Myers Squibb. Another anti-PD-1 drug candidate, Merck’s pembrolizumab (KEYTRUDA®) is currently under FDA Priority Review for NSCLC.

Conference Call
Tuesday, September 1, 2015 @ 8:30am Eastern Time

Toll Free:	888-572-7025
International:	719-457-2085
Conference ID:	9960179
Webcast:	http://ir.heatbio.com/events-presentations

Replays *(Available through September 15, 2015):*

Toll Free:	877-870-5176
International:	858-384-5517
Conference ID:	9960179

About the Trial
The trial is an ongoing multicenter, open label Phase 1b trial evaluating the safety and efficacy of HS-110 in patients with non-small cell lung cancer patients who have failed at least one other therapy. The trial is designed to evaluate HS-110 in combination with multiple tumor anti-immunosuppressive and checkpoint agents through a single protocol. In one arm, patients with low baseline TIL expression will receive HS-110 plus nivolumab. In another arm, patients with a high baseline TIL expression will receive HS-110 plus nivolumab.

About Viagenpumatucel-L (HS-110)
Viagenpumatucel-L (HS-110) ImPACT-modified cell lines are designed to stimulate a patient's immune system to activate a cytotoxic T-cell response against a range of antigens known to be expressed by a high proportion of patients with non-small cell lung cancer (NSCLC). The backbone cell line for HS-110 was selected based on overlapping antigen expression in patient tumor specimens, including known and unknown antigens, and functions dually as an antigen delivery vehicle and adjuvant, to stimulate the immune system. By addressing the underlying genetic and antigenic heterogeneity within tumors, *ImPACT* vaccines can potentially treat all patients, a significant advantage over single antigen therapies.

About Heat Biologics, Inc.
Heat Biologics, Inc. (www.heatbio.com) is a clinical-stage biopharmaceutical company focused on developing novel, "off-the-shelf" *ImPACT*™ and *ComPACT* platform based therapeutic vaccines to combat a wide range of cancers. Our *ImPACT*™ Therapy is designed to deliver live, genetically-modified, irradiated human cells that are reprogrammed to "pump out" a broad spectrum of cancer-associated antigens delivered via a potent immune adjuvant, gp96, to activate a cancer patient's immune system to recognize and kill cancerous cells. *ComPACT* Therapy is designed to deliver T-cell priming and co-stimulatory molecule in a single product. Heat is conducting a Phase 1b trial of its viagenpumatucel-L (HS-110) cancer vaccine in patients with non-small cell lung cancer in combination with checkpoint inhibitors and a Phase 2 trial with its vesigenurtacel-L (HS-410) in patients with non-muscle invasive bladder cancer.

Forward Looking Statements
This press release includes forward-looking statements 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 regarding the timing of enrollment, the number of patients to be enrolled, the expected release of top-line response rate and PFS data, the timing of an HS-110 registration-directed study in NSCLC and the potential of the *ImPACT* vaccines. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability for Heat's *ImPACT*™ Therapy to perform as designed, the ability to timely enroll patients and complete the clinical trial on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2014 and Heat's other filings with the SEC. 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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EXHIBIT 99.2

Combining HS-110 and anti-PD-1 in NSCLC

September 1, 2015

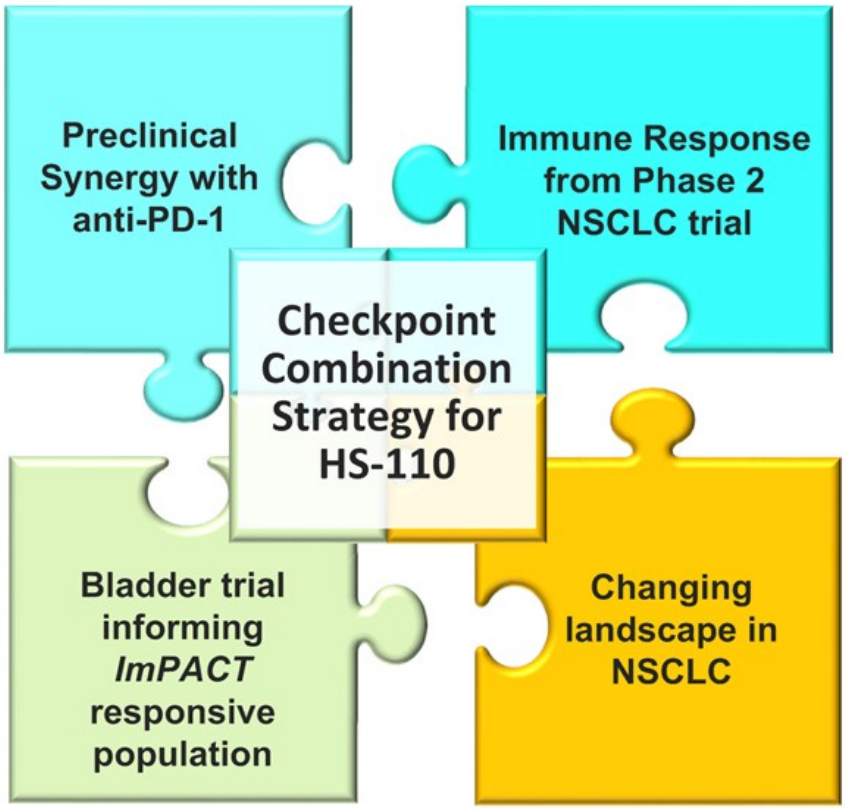
Forward Looking Statements

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 stem cells, 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.

Checkpoint Combination Rationale



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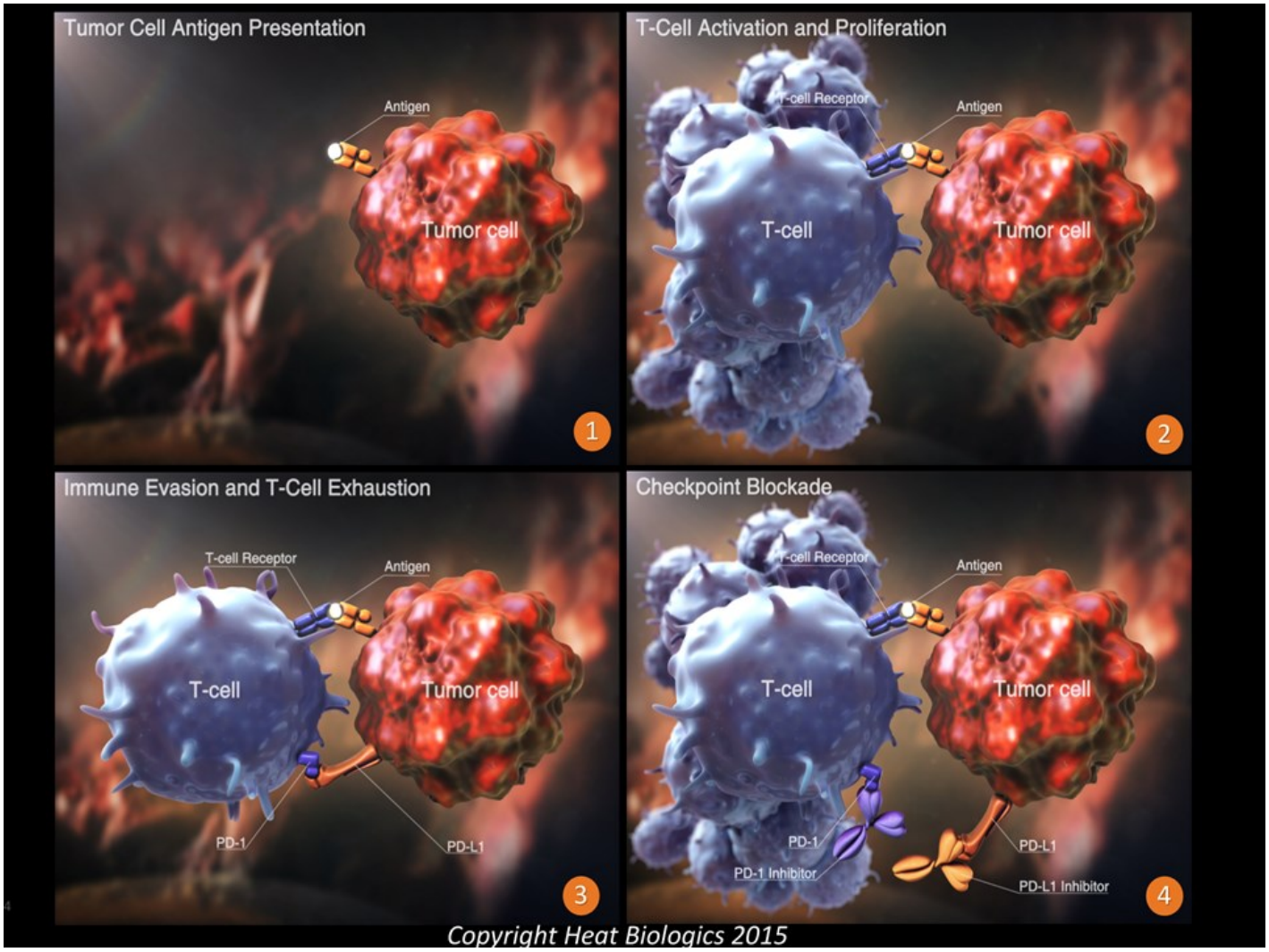
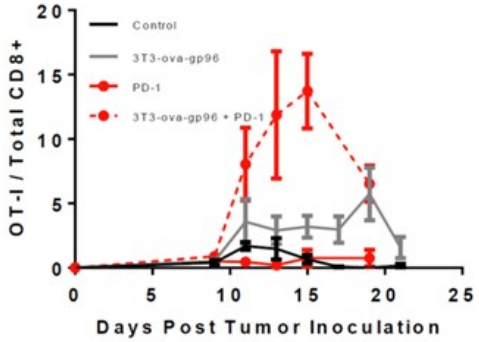
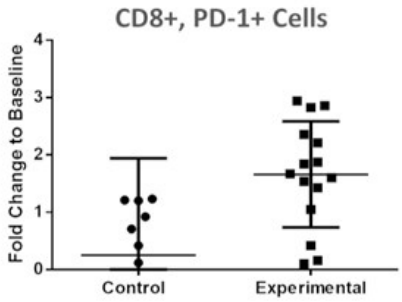


Scientific Support for HS-110 & Nivolumab Combination

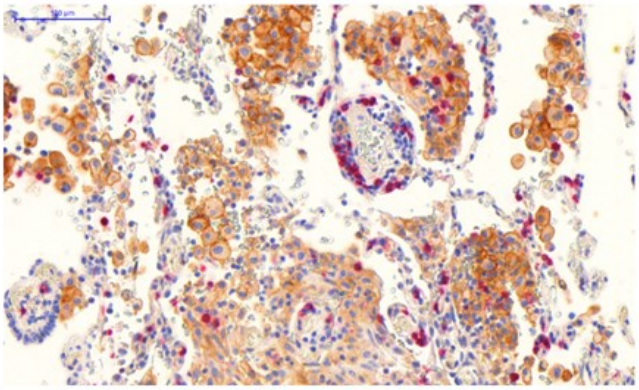


Schreiber T.H., et al. Keystone 2014



Cohen, R.B. et al, ASCO 2015

- Pre-clinical studies demonstrate synergy between *ImPACT* vaccines and anti-PD-1
- Phase 2 clinical data demonstrate that HS-110 treated patients upregulate PD-1 on CD8+ T cells
- Phase 2 tumor biopsies show strong PD-L1 staining



Phase 2 Tumor Biopsy from Patient Treated with HS-110

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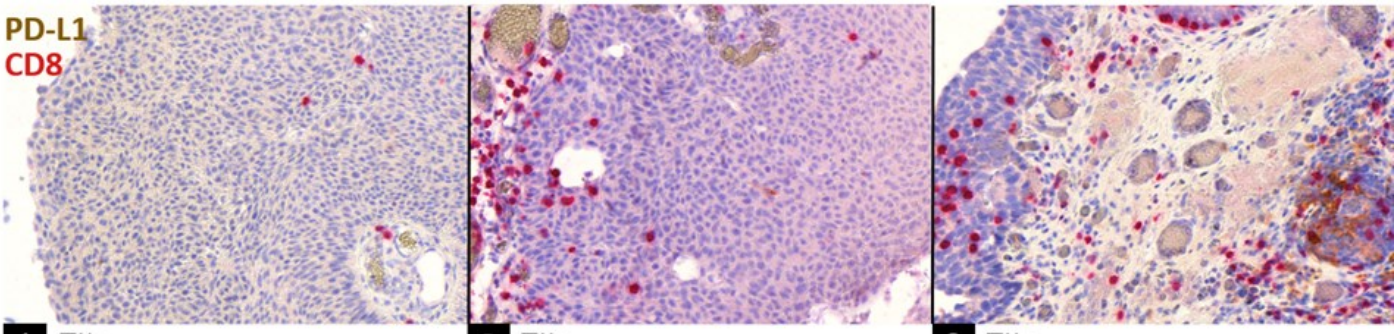
Bladder Cancer Patient Histology Data



1 TIL:
- Low/Negative

PD-L1:
- Low/Negative

2 TIL:
- Mid/High
- Excluded from tumor

PD-L1:
- Positive or Negative

3 TIL:
- High
- Infiltrating tumor

PD-L1:
- Positive

Responder/non-responder phenotype emerging:
Responder: $TIL^-/PD\text{-}L1^-$
Non-responder: $TIL^+/PD\text{-}L1^+$

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Design Intended to Broaden Responses to Nivolumab

T.H. Schreiber et al. / Seminars in Immunology 22 (2010) 105–112

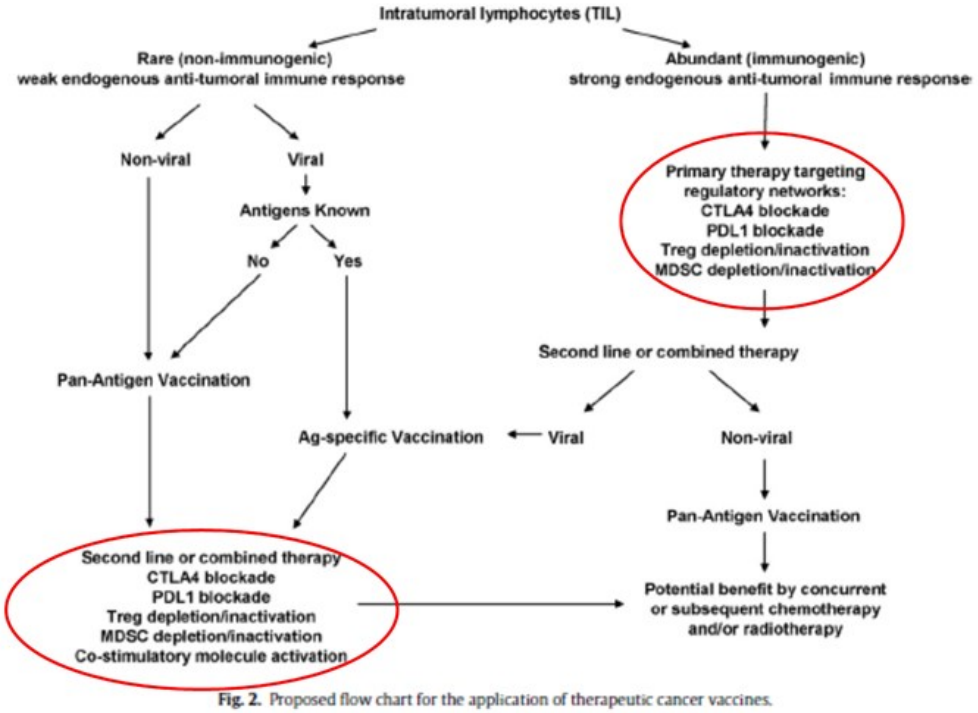

Fig. 2. Proposed flow chart for the application of therapeutic cancer vaccines.

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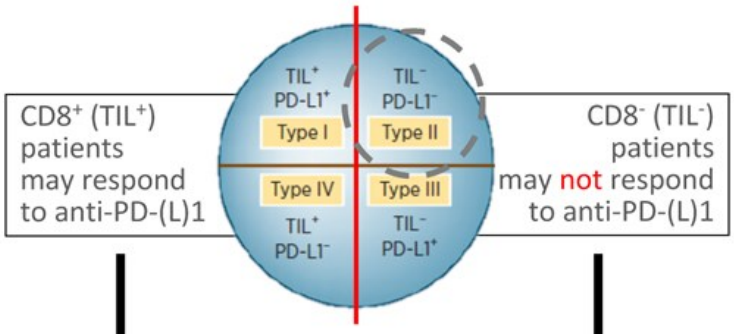
Design Intended to Broaden Responses to Nivolumab

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



Teng et al., 2015 Can Res
Gettinger et al., 2015 JCO

Approx. 50% PD-1 ORR

Approx. 10% PD-1 ORR

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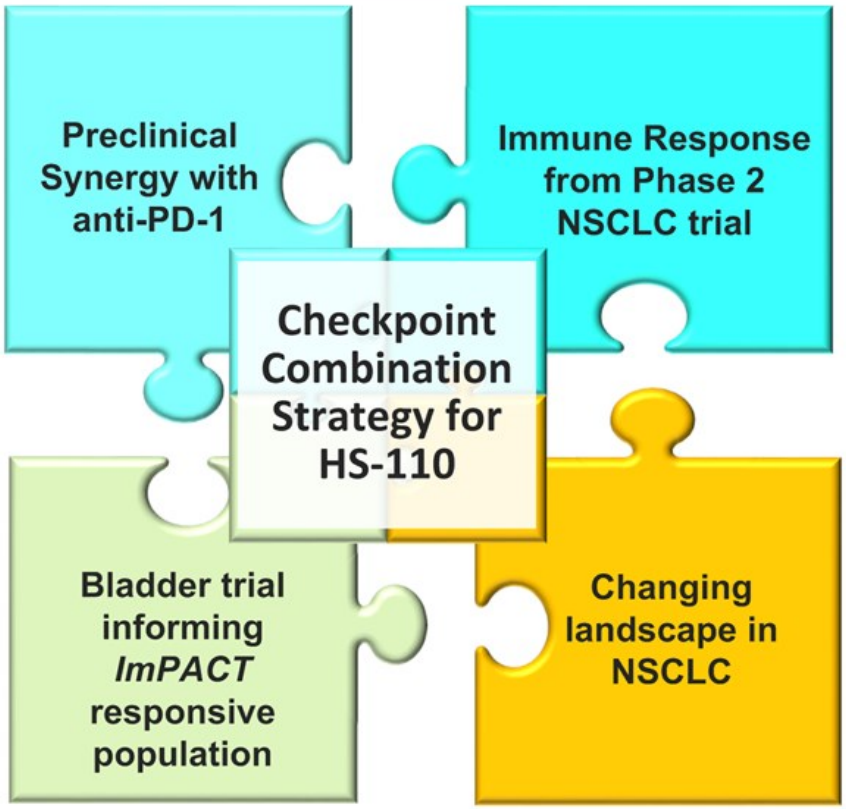
Checkpoint Combination Rationale



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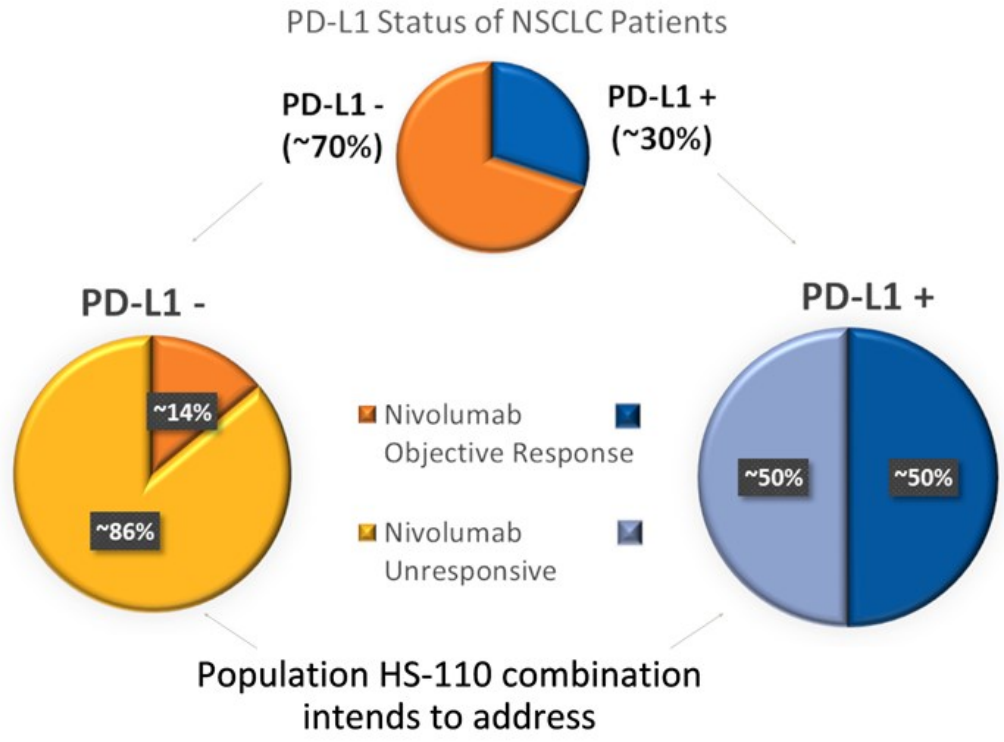
Response to Checkpoint Inhibitors by PD-L1 Status



Source: Velcheti et al. Lab Inv 2014; Gettinger et al., 2015 JCO

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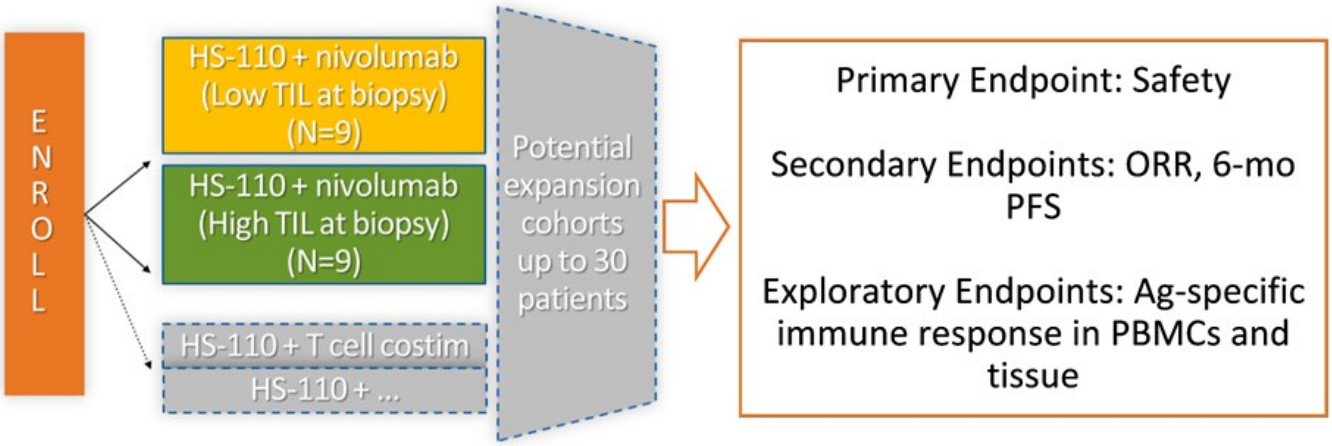
DURGA Multi-arm Combination Trial



- Provides operational platform to:
  - React quickly to changing landscape
  - Leverage potential synergy with PD-1 mAb
  - Evaluate TILs as a potential biomarker to improve response rate (Yale Cancer Center's Translational Immuno-Oncology Laboratory collaboration)
  - Expand cohorts based on efficacy signal

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Clinical Development Milestones

★ = NEW

		Milestone	Target Date
LUNG (NSCLC)	1	First dose combination with nivo in NSCLC (Durga)	31-Aug-2015
	2	Durga 18 pts enrolled	Q2 2016
	3	Durga immune response	Q2 2016
	4	Durga top-line readout for nivo (18 pts)	Q4 2016
	5	Ph 2 combo with cyclophosphamide readout (~65 pts)	Q4 2016
	6	Registration-directed trial initiation in NSCLC	Q4 2016
BLADDER (NMIBC)	7	Ph 2 Bladder Trial enrollment complete (75 pts)	Q3/Q4 2015
	8	Ph 1 Bladder Readout (10 pts)	Q4 2015
	9	Ph 2 Bladder Readout	Q4 2016
	10	Registration-directed trial initiation in NMIBC	Q4 2016
	11	Announce new *ComPACT* indication	Q1 2016

Heat Biologics

Summary

- First combination vaccine + nivolumab in NSCLC
- Strong preclinical/clinical rationale for combination
- Targeting patients unresponsive to checkpoints

- Data for nivo combo expected by end 2016
- Registration-directed trial initiation remains on schedule (end 2016/early 2017)
- Bladder program on track (readout Q4 2016)

- Cost savings from closing Ph 2 combination with cyclophosphamide to fund DURGA arms with nivolumab