
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): **May 29, 2015**

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”) will be making several investor presentations over the next few weeks. 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 |
|-----------------------------|---|
| <u>99.1</u> | 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: May 29, 2015

HEAT BIOLOGICS, INC.

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



NASDAQ:HTBX

Corporate Presentation

May 29, 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.

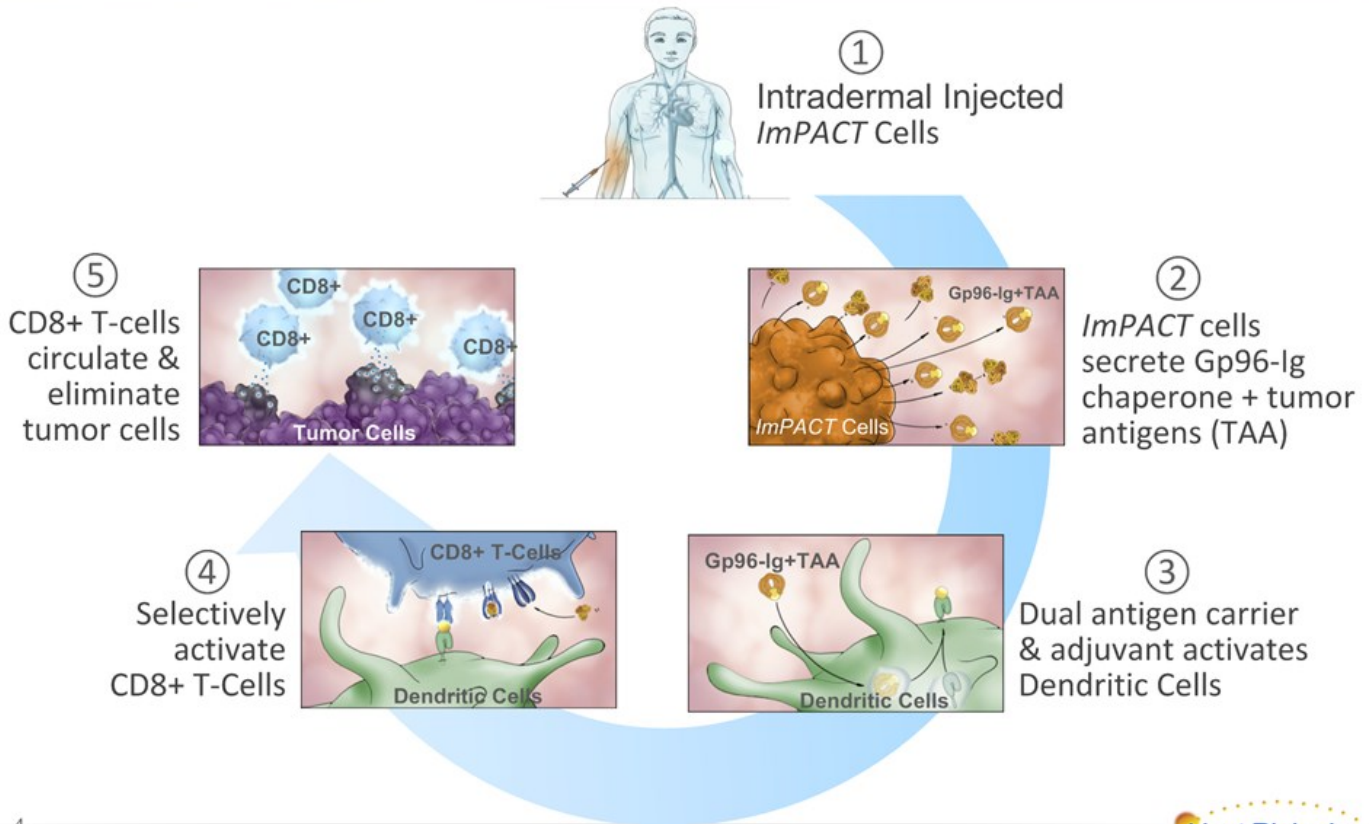
You should read carefully the factors described in the "Risk Factors" sections of our SEC Filings to better understand the risks and uncertainties inherent in our business.

Allogeneic Immune Pan-Antigen Cytotoxic Therapy “ImPACT” Platform

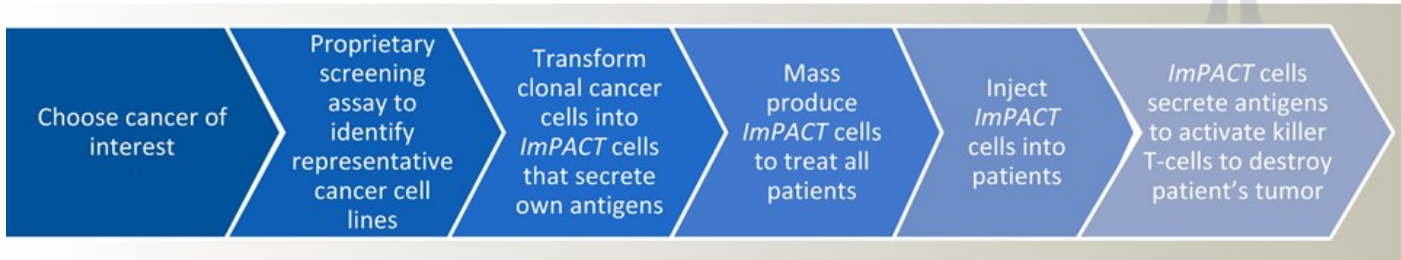
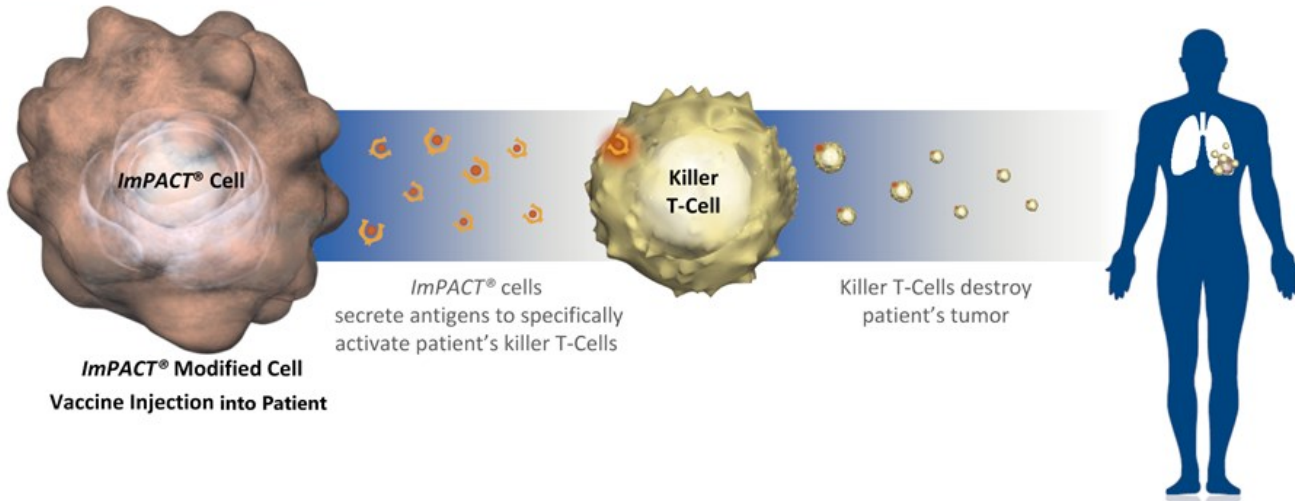
- Heat’s *ImPACT* allogeneic immunotherapy platform specifically designed to activate patient’s **CD8+ cytotoxic T cells** against multiple tumor antigens
- Two lead programs are actively enrolling patients in randomized, **controlled Phase II trials** in lung and bladder cancer
 - **Positive safety** profile with >80 patients dosed in 5 clinical studies with no treatment-related SAE’s, AE’s primarily Gr.1 injection site reactions
 - **Clinical evidence** validating mechanism of action in two ongoing randomized controlled Phase 2 programs in NSCLC and bladder cancer
- **Multiple near-term value-driving milestones** with clinical and pre-clinical milestones expected to be reported at least quarterly for the next two years

ImPACT Immunotherapy Platform

Specifically Designed to Activate Pan-Antigen CD8+ T-Cells to Kill Tumor Cells



ImPACT Drug Development and Manufacturing



HS-110 NSCLC (Lung Cancer) Program

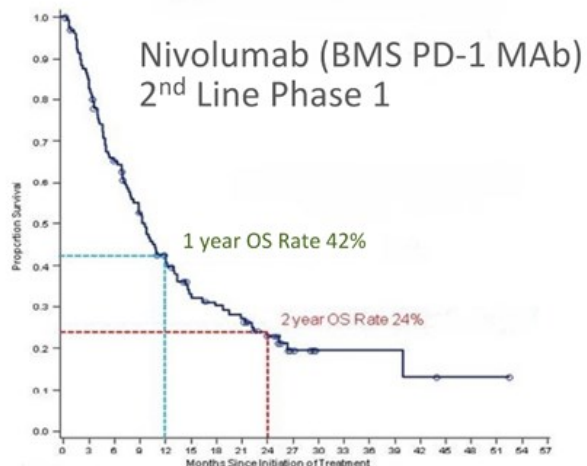
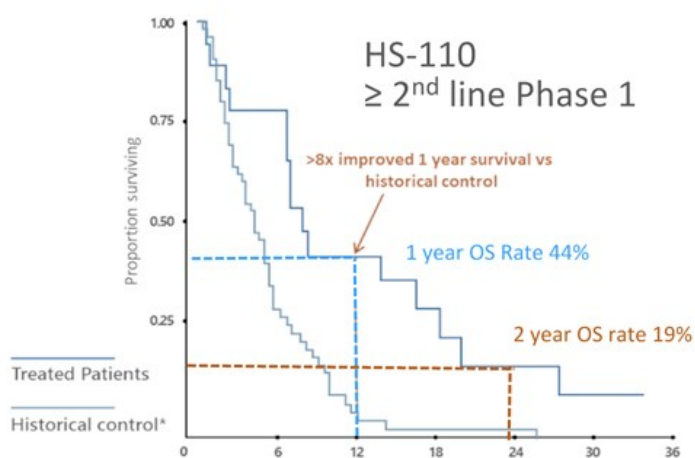
| Product Candidate | Cancer | Preclinical | Mfg | Phase 1 | Phase 2 | Phase 3 | |
|------------------------------|--------------------|---|-----|---------|---------|---------|--|
| ✓ HS-110 Viagenpumatucl-L | Lung (NSCLC) | 123 patient randomized control 3 rd line NSCLC | | | | | |
| HS-410 Vesigenurtacel-L | Bladder (NMIBC) | 100 patient randomized control NMIBC | | | | | |
| HS-110 Viagenpumatucl-L | Lung (NSCLC) | Multi-arm combination | | | | | |
| Multiple Programs | Undisclosed | | | | | | |

Opportunity in NSCLC

- T-cell activation for non-immunogenic tumors
- Combination with low-dose cyclophosphamide, known modulator of tumor-induced immunosuppression
- Success of checkpoint inhibitors demonstrates NSCLC responsive to immunotherapy

HS-110 Phase 1 Late-Stage Advanced NSCLC

Comparable Efficacy of HS-110 and Checkpoint Blockade

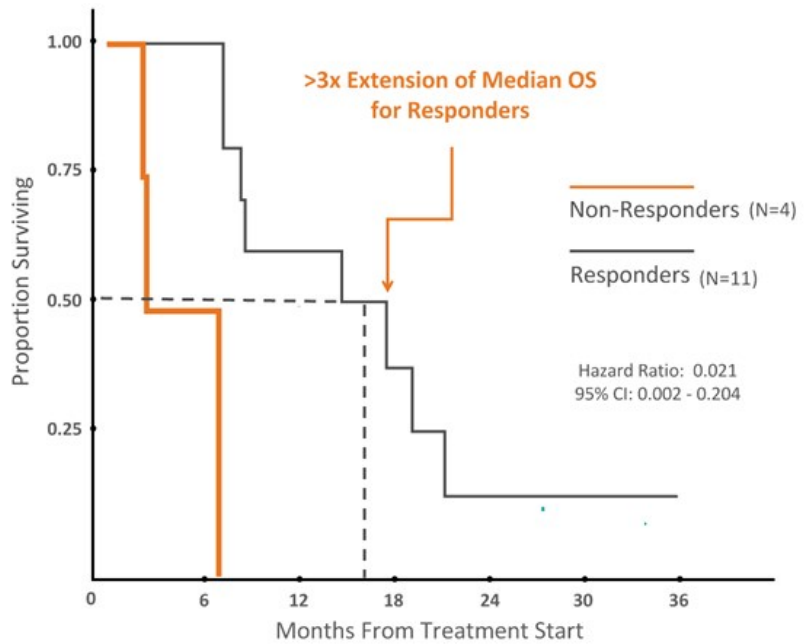


Scott Gettinger, Yale Cancer Center, 2014 ASCO annual Meeting

- **HS-110 well-tolerated** with no overt toxicity
- **Single agent clinical activity** in heavily pre-treated patients with advanced NSCLC
 - 7 of 15 patients stable disease after single course of therapy
- **Median 1 year overall survival rate** of patients in the study was 44% (95% CI: 21.6-65.1) comparing favorably to 42% rate in patients treated with Nivolumab in 2nd line

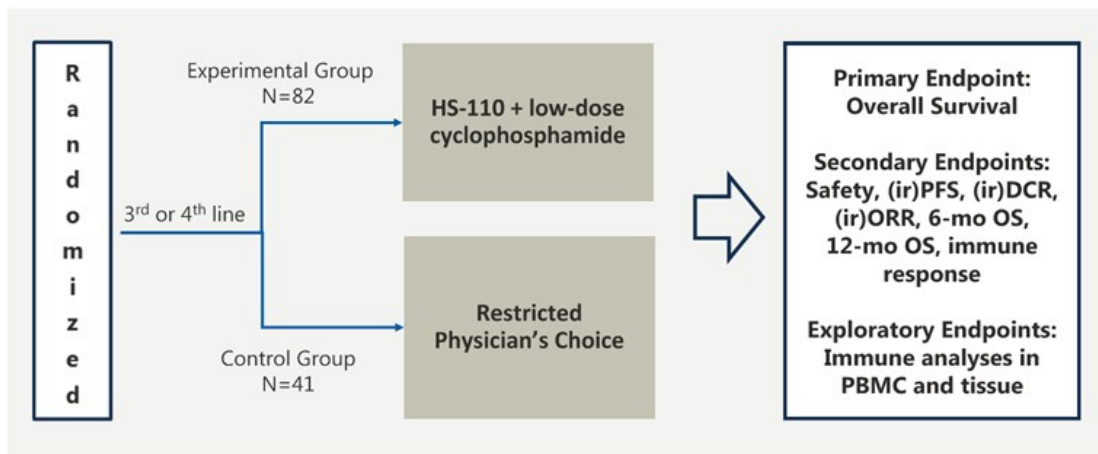
Immune Response Predictive of Survival

- **Peripheral blood immune response observed** in 73% (11 out of 15) of patients who completed their first course of therapy
- **Immune response predictive of survival**
 - Immune responders median overall survival = 16.9 months
 - Immune non-responders median overall survival = 4.5 months
- **Long-term survival**
 - Three patients survived >3 yrs.
 - One patient survived > 4 yrs.



Responders saw a threefold increase in median overall survival compared to non-responders in the trial, from 4.5 months to 16.9 months

Phase 2 HS-110/CY Combo NSCLC Design



Regimen

- Low-dose cyclophosphamide (CY) 50 mg daily for 7 days every 2 weeks for 12 weeks or until progression
- HS-110 10^7 cells weekly for 12 weeks then every 9 weeks until irPD or 12 months, whichever comes first
- Multi-center trial of ~25 sites in US and Australia
- Lead centers: University of Pennsylvania in USA; Peter MacCallum Cancer Center in AUS

Sample Size

- 123 patients randomized 2:1
- 80% power with $\alpha = 0.1$ to detect a 50% reduction in the risk of death
- Interim analysis for immune response after 14 and 40 patients randomized to experimental group

HS-410 Bladder Cancer Program

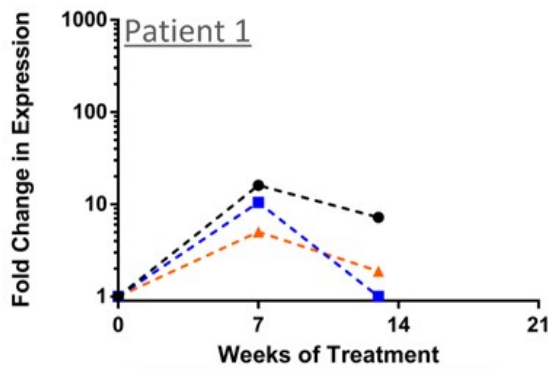
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| Multiple Programs | Undisclosed | | | | | | |

Opportunity in Bladder Cancer

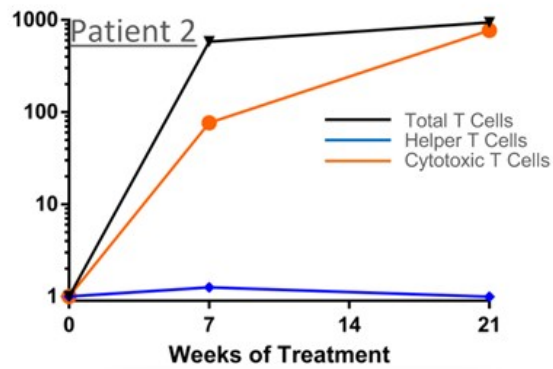
- Treat patients with minimal residual disease at a high-risk of recurrence within 2 years
- Leverage potential mechanistic synergy with BCG
- There has not been a new approved drug in non-muscle invasive bladder cancer in over 25 years

Evidence of CD8+ Tumor Infiltration in HS-410 Phase 1 Study

- Human data consistent with mechanism of action from preclinical models
- Tumor-infiltrating lymphocytes associated with clinical outcome

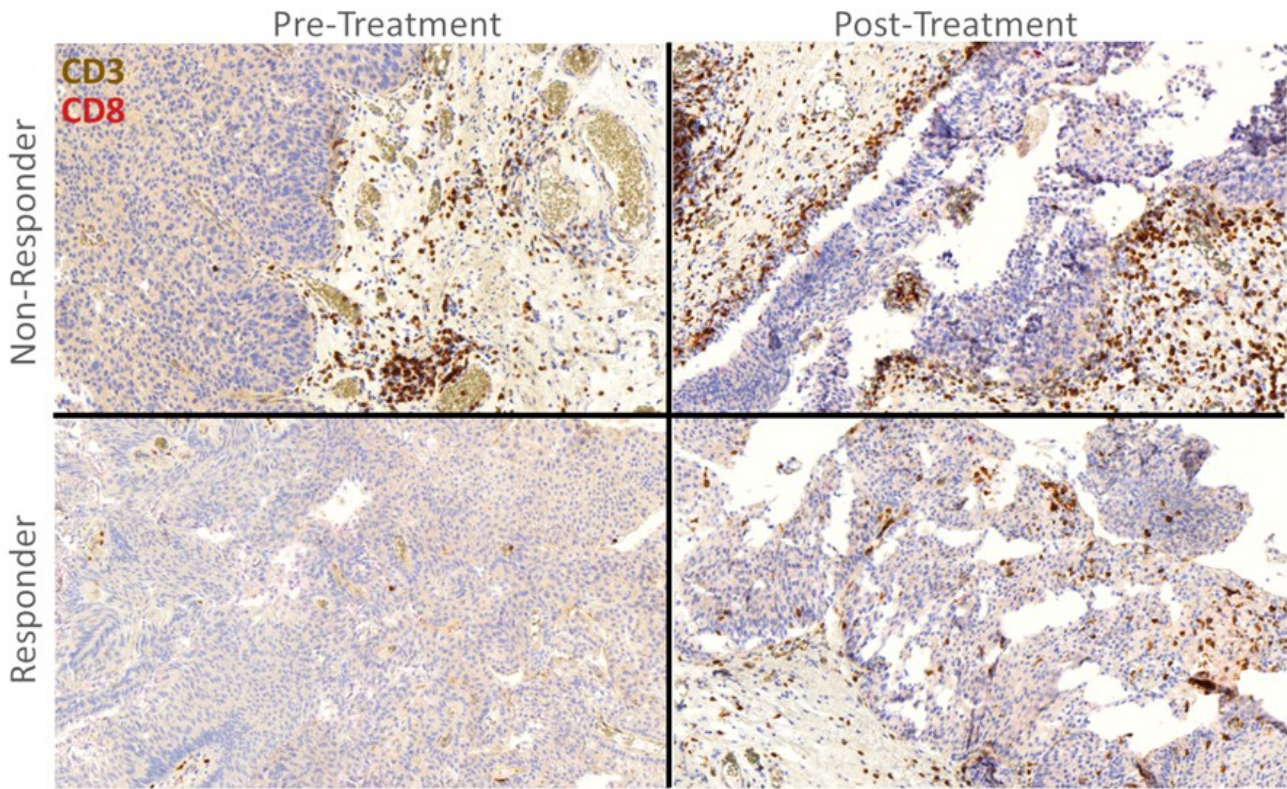


- T1 disease at diagnosis
- Downstaged to Ta at week 7
- Non-specific, low-level immune infiltrate
- Recurred at week 13

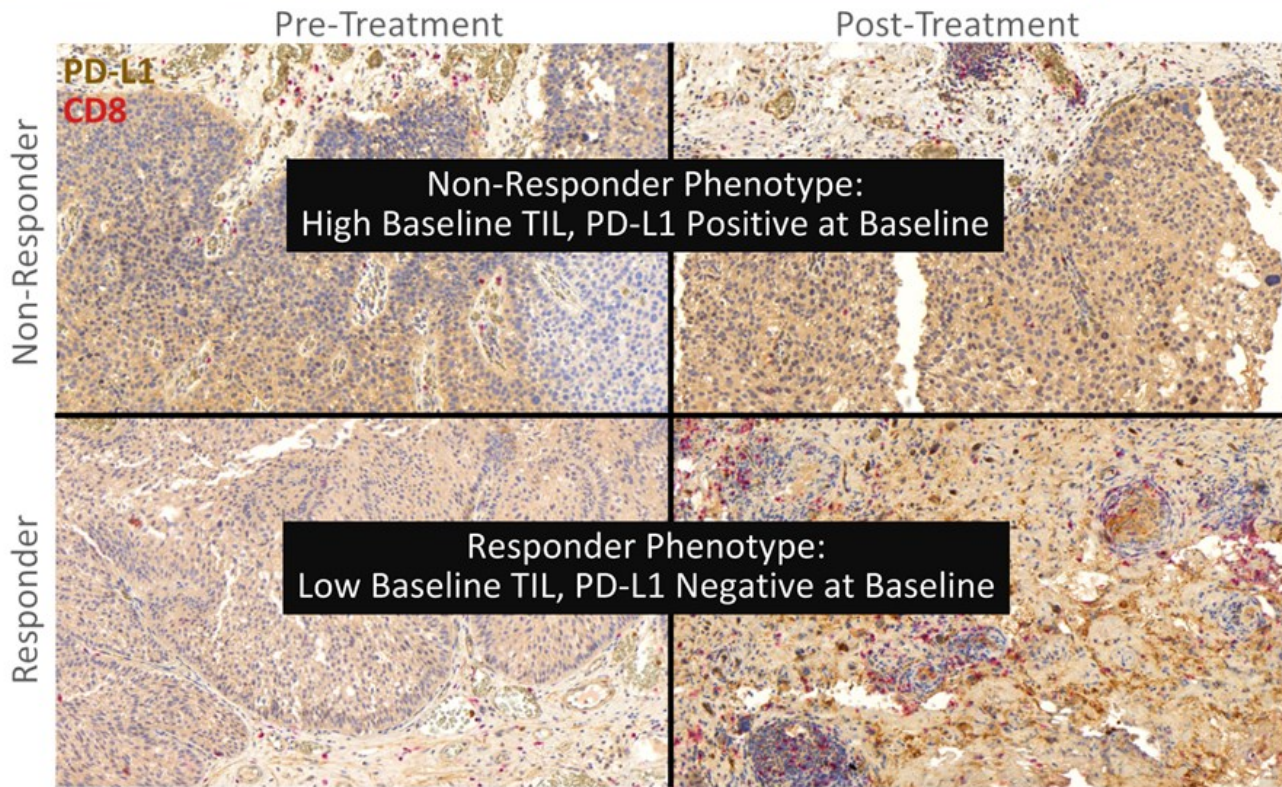


- T1 disease at diagnosis
- Downstaged to Ta at week 7
- Highly polarized, high-level immune infiltrate
- Disease free at week 21





Evidence of CD8+ Tumor Infiltration in HS-410 Phase 1 Study



Evidence of CD8+ Tumor Infiltration in HS-410 Phase 1 Study

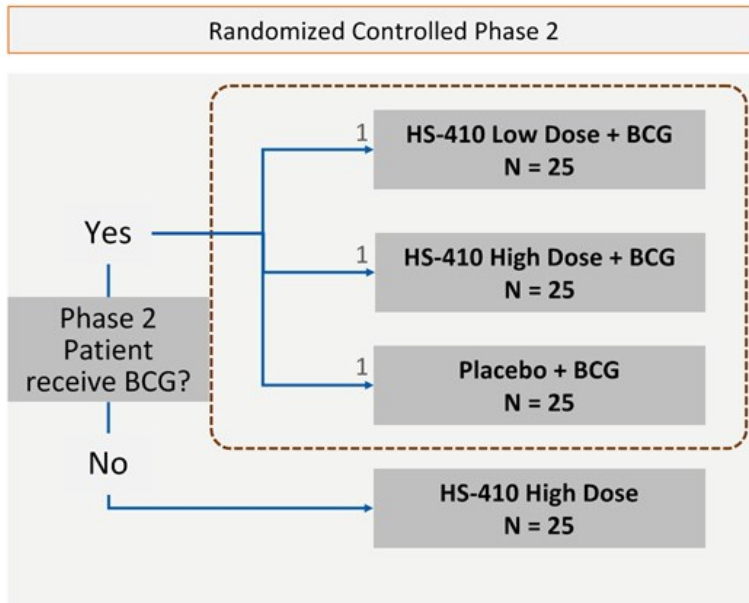


Injection Site Reactions – Delayed-Type Hypersensitivity

| | Week 1 Injection (L Thigh) | Week 2 Injection (R Thigh) | Week 3 Injection (R Buttocks) |
|--------------------------|---|---|--|
| ISR Start Date | 4 Days Post Injection | 1 Day Post Injection | Immediately Post Injection |
| Post Injection | No Reaction | No Reaction |  |
| One Week Post Injection |  |  | <p>The kinetics of the appearance of the injection site reactions are consistent with a delayed-type hypersensitivity reaction and cell-mediated immune responses.</p> |
| Two Weeks Post Injection |  | | |

Confidential

Phase 2 HS-410 Bladder Trial Design



Design

- Fast Track designation received
- Endpoints
 - 1-yr and 2-yr recurrence-free survival
 - Immune response in PBMC and tissue
- Dosing regimen 12 week induction followed by maintenance according to BCG schedule

Operations

- Multi-center trial of ~16 sites in US
- Lead center: University of Chicago School of Medicine
- Positive safety profile with no SAEs to-date

Heat Biologics (Nasdaq: HTBX)

2015 Milestones



Additional milestones may include partnership/collaboration opportunities, research developments and new data publications

ImPACT Clinical Findings

- Heat's *ImPACT* platform is mechanistically differentiated from all other vaccine platforms, providing specific CD8+ T cells activation to **multiple** tumor antigens
- Patient **tumor biopsies demonstrate specific CD8+ T cell infiltration** following treatment, and survival benefit in NSCLC consistent with reported data for PD-1 antibodies
- Frequent quarterly reporting of clinical milestones through 2016

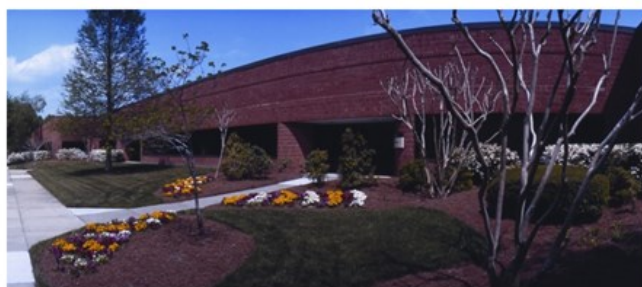
Heat Biologics (NASDAQ: HTBX): Company Snapshot

- Heat's *ImPACT* allogeneic "off-the-shelf" platform generates robust pan-antigen T cell activation for highly-differentiated mechanism of action
- Positive safety profile with >80 patients dosed in 5 clinical studies
- Clinical evidence validating mechanism of action in two ongoing randomized controlled Phase 2 programs in NSCLC and bladder cancer
- Multiple near-term value-driving inflection points
- Founded in 2008, completed IPO 2013

| | |
|------------------------|---------|
| Shares Outstanding | 8.39M |
| Share Price* | ~\$6.63 |
| Market Capitalization* | ~\$51M |
| Cash as of 3/31/15** | ~\$21M |
| Enterprise Value* | ~\$30M |

**As of May 21, 2015*

***Does not include \$7.5 million milestone-based debt facility*



Management and Advisors

| | |
|--|---|
| Jeff Wolf <i>Founder & CEO</i> | Founded several biomedical companies including Avigen, TyRx Pharma (sold to Medtronic), EluSys Therapeutics, GenerationOne |
| Anil Goyal, Ph.D. <i>VP Business Development</i> | 20+ years biotech business development experience: Serenex (acquired by Pfizer), Millennium Pharmaceuticals, Genome Therapeutics, Qualiber, Asclepis Pharmaceuticals, Merck |
| Taylor Schreiber, M.D., Ph.D. <i>VP Research & Development</i> | Co-developer <i>ImPACT</i> and TNFRSF25 technologies; 10+ years laboratory experience; Author numerous immunology and immunotherapy abstracts and publications |
| Melissa Price, Ph.D. <i>VP Clinical & Regulatory Affairs</i> | 14+ years in oncology clinical development in biotech and CRO space: INC Research, Novaquest, Attenuon |

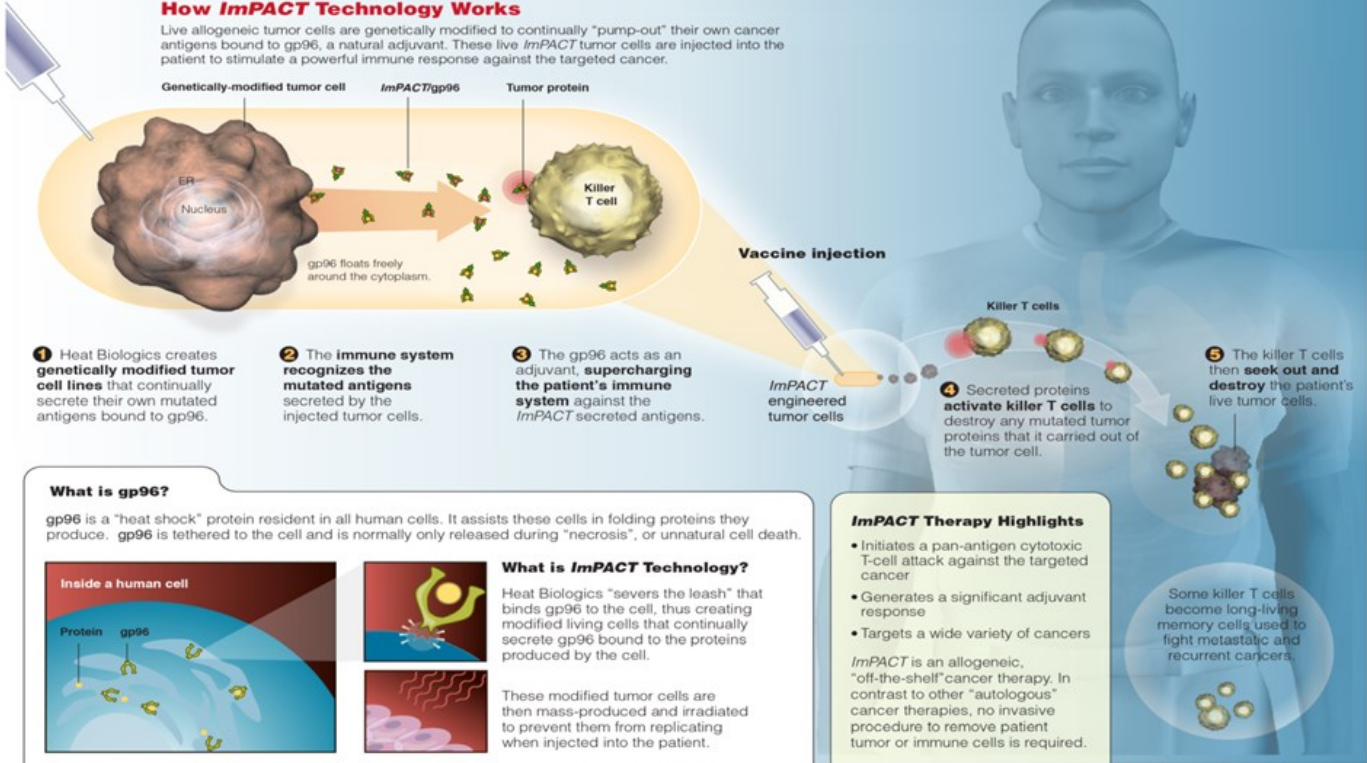
Scientific And Clinical Advisors

- **Eckhard R. Podack, M.D., Ph.D. (Chair)**
University of Miami School of Medicine
- **John Nemunaitis, M.D.**
Mary Crowley Cancer Research Center
- **Justin Stebbing, M.D., Ph.D.**
Imperial College, London
- **Gary Acton, M.D.**
Cancer Research UK, former CMO of Antisoma
- **Roger Cohen, M.D.**
University of Pennsylvania, Abramson Cancer Center
- **Llew Keltner, M.D., Ph.D.**
EPISTAT
- **Mark Schoenberg, M.D.**
Albert Einstein College of Medicine

Heat Biologics' proprietary Immune Pan Antigen Cytotoxic Therapy (ImPACT) reprograms live "allogeneic" cancer cells to continually secrete their own antigens bound to heat shock protein gp96 to seek out and destroy a variety of tumors.

How ImPACT Technology Works

Live allogeneic tumor cells are genetically modified to continually "pump-out" their own cancer antigens bound to gp96, a natural adjuvant. These live ImPACT tumor cells are injected into the patient to stimulate a powerful immune response against the targeted cancer.

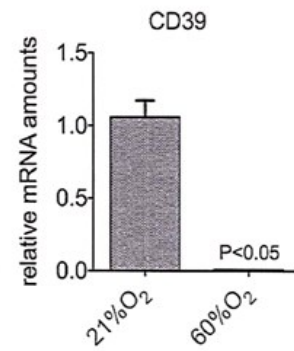
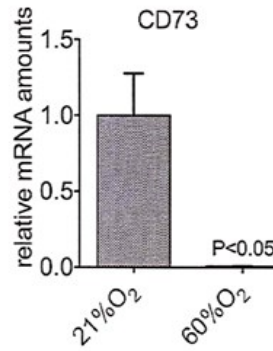
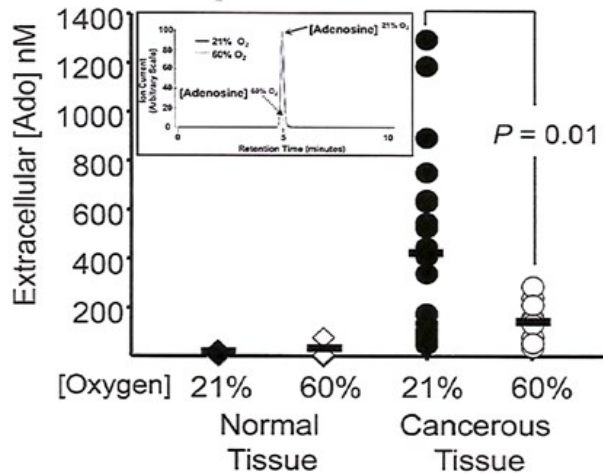


Thank you

for more information visit www.heatbio.com

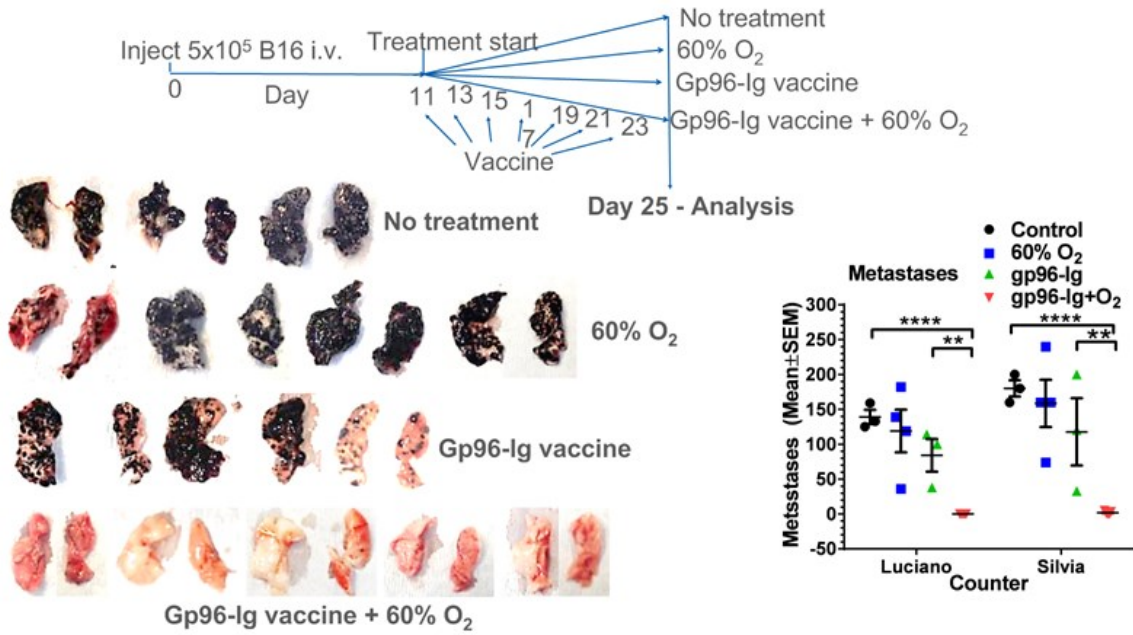
Appendix

60% O₂ down-regulates Adenosine, CD73 and CD39 in the TME in mice models

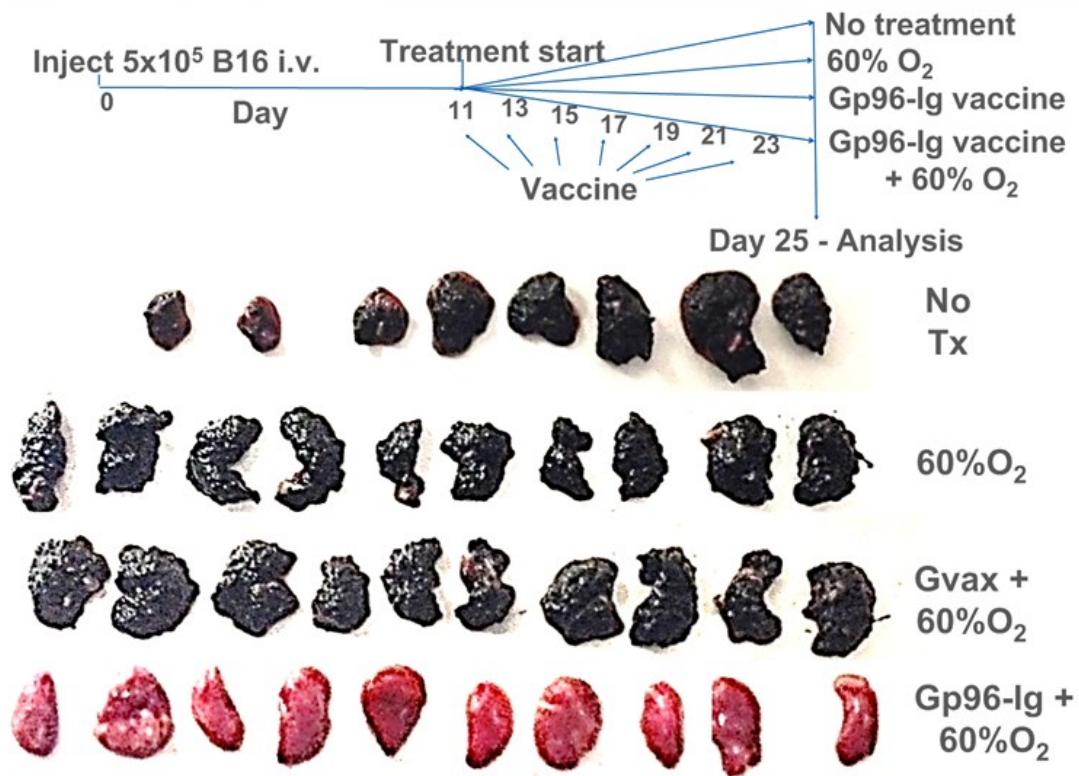


Hatfield et al J.Mol.Med. 2014

Tumor remission by combination treatment with gp96-Ig vaccine + 60% O₂ in mice models

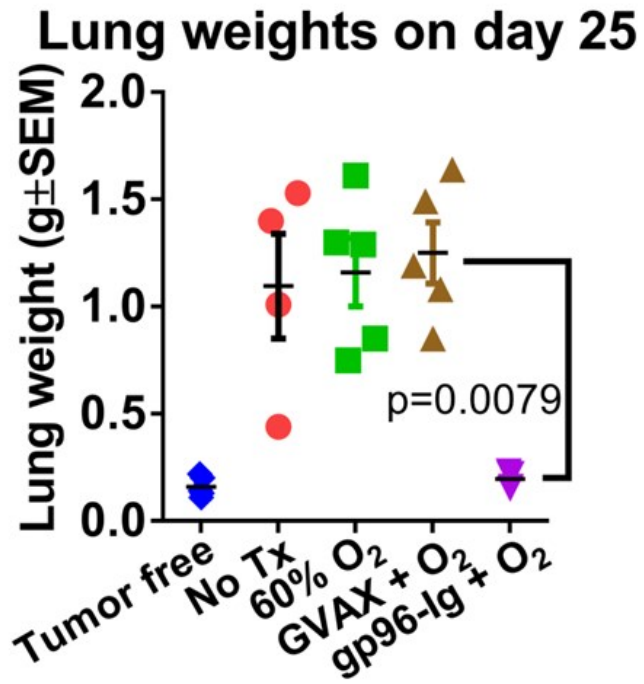


Gp96-Ig versus GVAX



Eckhard R Podack, *Phacilitate Immunotherapy*, 2015

Gp96-Ig + 60% O₂ restores normal lung weight in mice models



Inhibition of CTL by Hypoxia induced Adenosine

