

April 18, 2018



# Heat Biologics Announces Upcoming Milestones Following Positive Interim Phase 2 Results for HS-110

- *Plans Interim Lung Cancer Phase 2 Readout in Q4 2018 and Final Readout in Q2 2019*
- *Expects to File IND and Enroll First Patient in ComPACT Trial in Q4 2018*
- *Anticipates Receipt of \$6.9 Million in CPRIT Grant Funds in Q3 2018 to Support Filing of IND for PTX-35 in Q1 2019*

**DURHAM, NC / ACCESSWIRE / April 18, 2018/ [Heat Biologics, Inc.](#)** (NASDAQ: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, today provided guidance on upcoming clinical milestones for HS-110 in non-small cell lung cancer (NSCLC), its *ComPACT*™ platform, as well its Pelican subsidiary's co-stimulator antibody, PTX-35.

Anticipated Phase 2 NSCLC milestones include an interim data readout in Q4 2018 and a final Phase 2 data readout in Q2 2019, followed by a Phase 3-ready NSCLC program in Q3 2019. Expected PTX-35 milestones include receipt of \$6.9 million in CPRIT grant funds to support the enrollment of the first patient in a Phase 1 clinical trial in Q1 2019 and an interim data readout in Q3 2019. Additionally, Heat plans on enrolling its first patient in its *ComPACT* trial in Q4 2018 and anticipates an interim data readout in Q2 2019.

Jeff Wolf, Heat's CEO, commented, "The next four quarters are shaping up to be very exciting, with events that we believe will be transformational for our company. Earlier this year we reported positive interim results from the Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®), in patients with advanced NSCLC. We observed some potentially very exciting data with this combination that points to the opportunity to use this combined therapy in a very underserved population of NSCLC patients."

"Given all the recent progress, I am pleased to announce these upcoming milestones for the next 4 quarters. Importantly, we believe each of these milestones will help drive shareholder value. At the same time, we are witnessing advancements in the immuno-oncology landscape that are resulting in a growing interest in our technology across the industry, and, hence, we strongly believe our assets will play an important role in the future of combination immunotherapies."

## Anticipated milestones:

### Q3 2018:

- Receive \$6.9M in CPRIT (Cancer Prevention Research Institute of Texas) grant funds

#### **Q4 2018:**

- Interim Phase 2 NSCLC data readout
- IND filing for first *ComPACT* trial
- Enroll first patient in *ComPACT* trial

#### **Q1 2019:**

- PTX-35 IND filing
- Enroll first patient in PTX-35 trial

#### **Q2 2019:**

- Complete enrollment in Phase 2 NSCLC trial
- Phase 2 NSCLC data readout
- Interim *ComPACT* data readout

#### **Q3 2019:**

- Interim PTX-35 data readout

#### **About Heat Biologics, Inc.**

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using of CD8+ "Killer" T-cells. Our T-Cell Activation Platform (TCAP) produces therapies designed to turn "cold" tumors "hot" and be administered in combination with checkpoint therapies and other immuno-modulators to increase their effectiveness. HS-110 is our first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Our *ComPACT* technology is the first potential, dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product. We are currently enrolling patients in our Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®). 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. We also have numerous pre-clinical programs at various stages of development. For more information, please visit [www.heatbio.com](http://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 regarding the following anticipated milestones: interim Phase 2 NSCLC data readout in Q4 2018, completion of enrollment in Phase 2 NSCLC trial in Q2 2019, a Phase 2 NSCLC data readout in Q2 2019, a Phase 3-ready NSCLC program in Q3 2019, expected receipt of \$6.9 million in CPRIT grant funds to support the enrollment of the first patient in Phase 1 clinical trial in Q1 2019, IND filing for Heat's *ComPACT* trial in Q4 2018, enrollment of the first patient in Heat's

*ComPACT* trial in Q4 2018, interim *ComPACT* data readout in Q2 2019, PTX-35 IND filing in Q1 2019, enrollment of first patient in IND PTX-35 trial, an interim PTX-35 IND data readout in Q3 2019.. 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 *ImPACT*® therapy 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, and its ability to retain its key scientists or management personnel, its ability to successfully integrate Pelican, and the other factors described in Heat's most recent annual report on Form 10-K and other 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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**SOURCE:** Heat Biologics, Inc.