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Heat Biologics Announces Additional Positive Top Line Phase 2 Data of HS-110 plus Nivolumab in Advanced NSCLC Patients

Prospectively Defined PD-L1 Positive Patients Achieved Median Overall Survival of 42 Months

DURHAM, NC / ACCESSWIRE / November 20, 2019 /Heat Biologics, Inc. (NASDAQ:HTBX), presented additional positive Phase 2 interim top line data from Cohort A of the Company's Phase 2 trial of its T-cell activating cell-based therapy, HS-110, in combination with Opdivo® (nivolumab) in advanced non-small cell lung cancer (NSCLC) at a poster session at the American Association for Cancer Research (AACR) Special Conference on Tumor Immunology and Immunotherapy on November 19, 2019 available at https://www.heatbio.com/technology/scientific-publications. Cohort A enrolled only previously treated patients who have never received a checkpoint inhibitor (CPI).

The Company reported median overall survival (mOS) of 16.9 months with 50% of patients censored with median follow up of 17 months. This compares favorably to the 12.2 months mOS reported in the Checkmate 057[i] study with Bristol-Myers Squibb's nivolumab (Opdivo®) alone in a similar patient population. The Company also reported an objective response rate (ORR) per iRECIST of 22%, and a disease control rate (DCR) of 48%, with tumor shrinkage observed in 46% of patients.

Moreover, mOS of patients experiencing dermal injection site reactions (ISR) was 42.1 months. Statistically significant improvement in progression-free survival (PFS) and mOS was observed compared to those without ISR (Hazard Ratio = 0.51, p=0.042 and Hazard Ratio = 0.14, p <0.0001, respectively).

Jeff Hutchins, Ph.D., Heat's Chief Scientific and Operating Officer commented, "The data from Cohort A is extremely encouraging and builds upon our recently announced data in Cohort B, a population consisting of patients who previously progressed on a checkpoint inhibitor and were re-challenged with HS-110 plus nivolumab. Of special interest in Cohort A is a prospectively defined subset of PD-L1 positive patients who achieved a median overall survival of 42.1 months (95% CI; 15.8 - 42.1). This is particularly compelling when compared to overall survival rates in published literature of 1st or 2nd line checkpoint inhibitor monotherapy."

Highlights for Cohort A patients are presented below:

- Median Overall Survival of 16.9 months (50% of patients still alive with median follow

up of 17 months)
    - Median overall survival of ISR positive patients was 42.1 months (95% CI; 15.8 - 42.1) vs. an ISR negative mOS of 5.9 months (95% CI; 1.4 - 11.6) (Hazard Ratio = 0.14, p <0.0001)
    - A prospectively defined analysis of PD-L1 negative vs. PD-L1 positive showed a difference in mOS of 16.9 months (95% CI; 5.5 - unk) to 42.1 months (95% CI; 1.6 - 42.1), respectively
- Objective Response Rate by iRECIST of 22% and DCR of 48%
- Tumor shrinkage in 46% of patients
- Patients who achieved stable disease or better showed statistically significant decreases in peripheral blood T cell subsets from baseline while on combination treatment

Jeff Wolf, Heat's CEO, commented, "We are strongly encouraged by this latest data release and believe the data from both Cohorts A and B will be helpful as we advance partnership and collaboration discussions."

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 belief that the data from both Cohorts A and B will be helpful as we advance partnership and collaboration discussions and the potential benefits of our product candidates 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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[i] Brahmer, J., Reckamp, K.L., Baas, P. et al,**Nivolumab versus docetaxel in advanced squamous-cell non-small-cell lung cancer.** *N. Engl. J. Med.* 2015;373:123-135

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