May 29, 2020

Heat Biologics Presents Positive Survival Benefit for HS-110 in Combination with Nivolumab in Phase 2 Lung Cancer Trial at 2020 American Society of Clinical Oncology (ASCO) Annual Meeting

- ***Median overall survival of 28.7 months in previously treated checkpoint inhibitor naïve non-small cell lung cancer patients***
- ***Significantly greater median overall survival of 42.1 months observed in patients with injection site reaction***
- ***Planning to engage FDA for end-of-phase 2 meeting***

DURHAM, NC / ACCESSWIRE / May 29, 2020 /Heat Biologics, Inc. ("Heat") (NASDAQ:HTBX), a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, including multiple oncology product candidates and a novel COVID-19 vaccine, today presented its latest data at the ASCO Annual Meeting. The poster presentation can be viewed on the ASCO meeting website at: https://meetinglibrary.asco.org/record/184864/poster and on Heat Biologics' website at: https://www.heatbio.com/product-pipeline/scientific-publications

HS-110 is an "off-the-shelf" allogeneic cell-based therapy designed to activate patients' immune system against multiple cancer testis antigens (CTAs) to elicit a diverse and robust T-cell attack against tumor cells. A Phase 2 trial of HS-110 in combination with Bristol-Myers Squibb's (BMS) Opdivo® (nivolumab) for multiple treatment settings in advanced non-small cell lung cancer (NSCLC) is ongoing, with enrollment of this trial completed in July 2019.

This data demonstrated that significant survival benefit was observed in a cohort of previously treated, checkpoint inhibitor (CPI) naïve patients with advanced NSCLC; with a median overall survival (mOS) of 28.7 months for the intent-to-treat (ITT) patients (N = 47). This data compares favorably with published data of Checkmate 057, which reported a mOS of 12.2 months in patients who received nivolumab as single agent in a similar treatment setting. Notably, a statistically significant survival benefit with mOS of 42.1 months was observed in patients with injection site reaction (p = 0.0001). Exploratory biomarker analyses showed that overlapping CTA expression in patients' tumors at baseline with HS-110, as well as the expression of a specific CTA were both associated with statistically significant improved overall survival (p = 0.028 and 0.008, respectively).

"Our exploratory biomarker analysis solidly establishes additional clinical evidence for the HS-110 mechanism of action," said Jeff Hutchins, Chief Scientific and Operating Officer of Heat. "This extended mOS also suggests that HS-110 treatment in combination with a CPI

should be considered for any solid tumor type with sufficient CTA overlap with HS-110."

This study has completed enrollment, and 21 of the 47 patients enrolled (45%) are still alive as of this data cut. HS-110 now has a positive safety profile in over 200 patients, and combination of HS-110 and nivolumab appears to be safe and well-tolerated.

"This updated data demonstrates the potential utility of HS-110 in combination with a checkpoint inhibitor as a frontline treatment for NSCLC", said Jeff Wolf, Chief Executive Officer of Heat. "Heat is planning an end-of-phase 2 meeting with the FDA to discuss registration trial design."

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system. The company's gp96 platform is designed to activate immune responses against cancer or pathogenic antigens. Multiple product candidates in development leveraging the gp96 platform, including HS-110 in phase 2, HS-130 in phase 1, and COVID-19 vaccine program in preclinical development. In addition, Heat Biologics is also developing a pipeline of proprietary immunomodulatory antibodies, including PTX-35. For more information, please visit www.heatbio.com.

Forward Looking Statement

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, expectation, and assumptions and include statements such as the extended mOS suggesting that HS-110 treatment in combination with a CPI should be considered for any solid tumor type with sufficient CTA overlap with HS-110, the potential utility of HS-110 in combination with a checkpoint inhibitor as a frontline treatment for NSCLC, the planned end-of-phase 2 meeting with the FDA to discuss registration trial design and Heat's gp96 platform activating immune responses against cancer or pathogenic antigens. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, 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, the ability of Heat together with researchers at the University of Miami to develop a proprietary COVID-19 vaccine, 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 continue to maintain its listing on the Nasdaq Capital Market and its ability to retain its key scientists or management personnel, and the other factors described in Heat's most recent annual report on Form 10-K for the year ended December 31, 2019 filed with the SEC, and other

subsequent filings with the SEC. The information in this release is provided only as of the date of this release, and Heat 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.

Media and Investor Relations Contact

David Waldman
+1 919 289 4017
investorrelations@heatbio.com

SOURCE: Heat Biologics, Inc.

View source version on accesswire.com:
https://www.accesswire.com/591882/Heat-Biologics-Presents-Positive-Survival-Benefit-for-HS-110-in-Combination-with-Nivolumab-in-Phase-2-Lung-Cancer-Trial-at-2020-American-Society-of-Clinical-Oncology-ASCO-Annual-Meeting