February 9, 2021

Heat Biologics Announces Positive Interim Survival Data from Ongoing HS-110 Phase 2 Non-Small Cell Lung Cancer Trial

Median overall survival of 24.6 months in previously treated checkpoint inhibitor naïve non-small cell lung cancer patients who received HS-110 in combination with nivolumab

DURHAM, NC / ACCESSWIRE / February 9, 2021/ 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 reported positive interim data of the Company's fully-enrolled Phase 2 trial of HS-110, in combination with Bristol-Myers Squibb's (BMS) OPDIVO® (nivolumab) in advanced non-small cell lung cancer (NSCLC). HS-110 is an "off-the-shelf" allogeneic cell-based therapy designed to activate patients' immune system against multiple cancer testis antigens to elicit a diverse and robust immune response against tumor cells.

Substantial survival benefit was observed in a cohort of previously treated, checkpoint inhibitor naïve patients with advanced NSCLC (Cohort A, N = 47). A median progression free survival (PFS) of 1.8 months and a median overall survival (OS) of 24.6 months was observed with a median follow-up time of 19.4 months. The one-year survival rate of Cohort A is 61.7%. The median OS data was 12.2 months and the 1-year survival rate was 50.7% in previously treated, advanced NSCLC patients who received nivolumab as a single agent, according to published data of the BMS CheckMate 057 study[1]. Our data suggests that addition of HS-110 to a checkpoint inhibitor has the potential to improve survival benefit for checkpoint inhibitor naïve NSCLC patients.

For NSCLC patients who had previously been treated with a checkpoint inhibitor and whose disease had subsequently progressed (Cohort B, N = 68), a median PFS of 2.8 months and median OS of 11.9 months was observed with a median follow-up time of 11.9 months. NSCLC patients whose disease progresses following checkpoint inhibitor therapy have limited treatment options[2]. Published data from other studies reported median OS of 6.8 to 9.0 months for NSCLC patients treated with chemotherapies after PD-(L)1 progression[3,4]. Our data of HS-110 in combination with nivolumab in Cohort B suggests potential treatment benefit for NSCLC patients whose disease progressed following treatment with PD-(L)1 therapy.

As of this data cut, 30% of the patients in Cohort A and 26% of the patients in Cohort B are still alive. HS-110 has a favorable safety profile and has been administered in approximately 200 patients to date. As of this data cut, there have been no treatment-related serious adverse reactions. A review of immune-related adverse events reported in the study raised

no safety concerns. The data to date demonstrate that combination of HS-110 and nivolumab is well-tolerated.

"We are thrilled to report this latest positive survival data from our Phase 2 trial of HS-110, in combination with Bristol-Myers Squibb's OPDIVO® (nivolumab) in advanced non-small cell lung cancer demonstrating HS-110's broad potential for providing multiple treatment options to NSCLC patients," stated Jeff Wolf, Chief Executive Officer of Heat Biologics. "HS-110 is the lead candidate in our portfolio of therapeutic products and vaccines utilizing Heat's gp96 technology platform and showcases the broad utility of this platform for NSCLC and potentially other types of cancer. We are currently evaluating possible Phase 3 registration pathways for HS-110 in combination with a checkpoint inhibitor and intend to review these plans with the FDA as well as potential partners."

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 infectious diseases. The Company has multiple product candidates in development leveraging the gp96 platform, including HS-110, which has completed enrollment in its Phase 2 trial, and a COVID-19 vaccine program in preclinical development. In addition, Heat is also developing a pipeline of proprietary immunomodulatory antibodies and cell-based therapies, including PTX-35 and HS-130 in Phase 1 clinical trials.

For more information, please visit: www.heatbio.com, and also follow us on Twitter.

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 potential of the addition of HS-110 to a checkpoint inhibitor to improve survival benefit for checkpoint inhibitor naïve NSCLC patients, the potential treatment benefit of HS-110 in combination with nivolumab for NSCLC patients whose disease progressed following treatment with PD-(L)1 therapy, HS-110's broad potential for providing multiple treatment options to NSCLC patients, possible Phase 3 registration pathways of HS-110 in combination with a checkpoint inhibitor and intended discussion of these plans with the FDA as well as potential partners and the broad utility of this platform for NSCLC and potentially other types of cancer.These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability of HS-110 when added to a checkpoint inhibitor to improve survival benefit for checkpoint inhibitor naïve NSCLC patients, the ability of HS-110 in combination with nivolumab to have a potential treatment benefit for NSCLC patients whose disease progressed following treatment with PD-(L)1 therapy, the ability of HS-110's to provide multiple treatment options to NSCLC patients, the ability of Heat to successfully design a registrational pathway for HS-110, the ability of Heat's platform to have utility for NSCLC and potentially other types of cancer , Heat's vaccine platform to provide protection against COVID-19, 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, especially in light of COVID-19, 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 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 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.

Reference

[1] Borghaei et al. Five-Year Outcomes from the Randomized, Phase III Trials CheckMate 017 and 057: Nivolumab Versus Docetaxel in Previously Treated Non-Small-Cell Lung Cancer. J Clin Oncol. 2021 Jan 15.

[2] NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer Version 2.2021-Dec 15, 2020.

[3] Costantini et al. Efficacy of next treatment received after nivolumab progression in patients with advanced nonsmall cell lung cancer. ERJ Open Res. 2018 Apr 20;4(2):00120-2017.

[4] Schvartsman et al. Response rates to single-agent chemotherapy after exposure to immune checkpoint inhibitors in advanced non-small cell lung cancer. Lung Cancer. 2017 Oct;112:90-95.

Media and Investor Relations Contact

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

SOURCE: Heat Biologics, Inc.