June 22, 2020

Heat Biologics Announces First Patient Treated in First-in-Human Clinical Trial of PTX-35

DURHAM, NC / ACCESSWIRE / June 22, 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 announced that the first patient has been treated in the Company's first-in-human Phase 1 clinical trial evaluating PTX-35, the first antibody product candidate developed by Heat Biologics' Pelican Therapeutics subsidiary.

This first-in-human study is expected to enroll up to 30 patients with advanced solid tumors refractory to standard of care. Eligible patients will be enrolled to receive PTX-35 every two weeks until disease progression. Escalating dose levels of PTX-35 will be explored until optimal immunological dose or maximum tolerated dose is established. The objectives of the study include safety evaluation, determination of the recommended Phase 2 dose as well as exploratory analyses of clinical benefit and immunological effect of PTX-35. This trial is supported by a $15.2 million grant from the Cancer Prevention and Research Institute of Texas (CPRIT).

Jeff Wolf, CEO of Heat Biologics, commented, "This is an important milestone as we advance our first antibody product candidate into clinical development. I am very pleased with our team's effort in accelerating the development of PTX-35 as well as the speed of execution to initiate our first-in-human study following FDA clearance of our Investigational New Drug (IND) Application. I believe that PTX-35, our potential first-in-class T-cell co-stimulatory antibody, will offer a differentiated approach to benefit cancer patients."

About PTX-35

PTX-35 is a novel, potential first-in-class antibody T-cell co-stimulator targeting TNFRSF25 (death receptor 3), a receptor that is preferentially expressed by antigen-experienced T cells. TNFRSF25 agonism leads to activation of antigen-experienced memory CD8+ T cells, which are instrumental for tumor destruction. Preclinical studies have demonstrated that PTX-35, in combination with antigen-driven immunotherapies, resulted in enhanced anti-tumor properties, including potent proliferation of antigen-specific T cells, production of effector cytokines and augmented effector immune function. A favorable safety profile was demonstrated in preclinical studies, with no deleterious cytokine release in mice, non-human primates or *in vitro* human immune cells.

A $15.2 million grant has been awarded by Cancer Prevention and Research Institute of Texas (CPRIT) to support the pre-clinical development, manufacturing and Phase 1 clinical development for PTX-35.

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 which has completed enrollment in its Phase 2 trial, HS-130 in Phase 1, and a COVID-19 vaccine program in preclinical development. In addition, Heat is also developing a pipeline of proprietary immunomodulatory antibodies, including PTX-35 which is enrolling in a Phase 1 trial. 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 expected enrollment in the trial, the potential of PTX-35 as a first-in-class antibody T-cell co-stimulator, and PTX-35 offering a differentiated approach to benefit patients. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including, the ability to successfully enroll and complete the first-in-human clinical trial of PTX-35 in solid tumors, 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.

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