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Heat Biologics Announces FDA Clearance of Investigational New Drug (IND) Application for PTX-35

PTX-35 represents a potential first-in-class agonistic antibody of TNFRSF25

DURHAM, NC / ACCESSWIRE / June 8, 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 U.S. Food & Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for PTX-35, developed by Heat's Pelican Therapeutics subsidiary. Pelican has near-term plans to initiate its Phase 1 clinical trial in patients with solid tumors.

PTX-35 is a novel, first-in-class agonist antibody targeting TNFRSF25, also known as death receptor 3 (DR3), 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 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.

Rahul Jasuja, PhD, CEO of Pelican Therapeutics, commented, "The mechanism of action for PTX-35 is highly differentiated compared to other co-stimulators. Activation of TNFRSF25 by PTX-35 in preclinical models leads to a more pronounced expansion of tumor antigen-specific cytotoxic, or "killer" T cells, resulting in enhanced tumor growth inhibition and prolonged survival. The team has delivered a robust IND package, demonstrating pre-clinical efficacy along with a favorable safety profile in mice and non-human primates."

Jeff Wolf, CEO of Heat, said, "PTX-35 is a potential first-in-class therapy that may provide additional treatment options for cancer patients. We are close to initiating our first-in-human clinical trial of PTX-35 in multiple solid tumors and look forward to providing further updates as we achieve anticipated milestones. We would like to thank Cancer Prevention Research Institute of Texas (CPRIT) for the $15.2 million grant to support the preclinical work, cGMP manufacturing and Phase 1 development of 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 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 potential of PTX-35 as a potential first-in-class therapy that may provide additional treatment options for cancer patients and near-term plans to initiate a Phase 1 clinical trial in patients with solid tumors. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including, the ability to successfully initiate 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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