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Heat Biologics Announces Initiation of the Lead Clinical Trial Site for PTX-35

Anthony Tolcher, M.D., FRCPC appointed as the lead investigator

DURHAM, NC / ACCESSWIRE / June 18, 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 initiation of the first clinical trial site for PTX-35. Anthony Tolcher, M.D., FRCPC, a medical oncologist and co-founder of NEXT Oncology, has been appointed the lead investigator for the Phase 1 clinical trial.

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.

Rahul Jasuja, PhD, CEO of Pelican Therapeutics, commented, "We are pleased to welcome Dr. Anthony Tolcher as the lead investigator for our PTX-35 Phase 1 trial. He is a distinguished medical oncologist with over 25 years of early drug development and clinical trial expertise and a principal investigator for 20 Phase 1 clinical studies of new agents that subsequently were FDA approved for the treatment of cancer, including Merck's pembrolizumab (Keytruda®). Dr. Tolcher has over 100 peer-reviewed publications in top scientific journals, and a proven track record of advancing multiple innovative oncology products through Phase 1. We believe NEXT Oncology under the leadership of Dr. Tolcher is an ideal site for our study and look forward to enrolling our first patient shortly."

Dr. Tolcher said, "PTX-35 is a promising product candidate that exquisitely targets TNFRSF25. This is a first-in-class antibody that targets an important pathway to activate antigen-experienced memory CD8+ T cells. I believe PTX-35 may provide additional treatment options for patients when current therapy does not work in controlling their cancers. Immunotherapy is the most exciting and a rapidly growing area of oncology and we are just beginning to see the potential for expanding new avenues and targets in harnessing the immune system for the treatment of cancer."

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 NEXT Oncology

NEXT Oncology is dedicated to the advancement of Phase 1 cancer research through clinical trials of anticancer agents with the goal of providing innovative developments in cancer treatment. Dr. Anthony Tolcher is a medical oncologist and co-founder of NEXT Oncology. He is dedicated to the advancement of new anticancer agents for patients whose current cancer therapy is no longer working to benefit them. Many of the initial Phase 1 studies of new agents that Dr. Tolcher was involved in were subsequently approved by FDA, including pembrolizumab (Keytruda®), copanlisib (Aliqopa®), trastuzumab emtansine (Kadcyla®), regorafenib (Stivarga®), liposomal vincristine (Marqibo®), cabazitaxel (Jevtana®), carfilzomib (Kyprolis®), gefitinib (Iressa®), erlotinib (Tarceva®) and eribulin (Halaven®). He is a reviewer for the Journal of Clinical Oncology, Clinical Cancer Research and Annals of Oncology, and chaired the Developmental Therapeutics Review Committee for the American Society for Clinical Oncology Annual Scientific Program. Dr. Tolcher has over 100 peer-reviewed publications in scientific journals.

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 in Phase 1. 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 NEXT Oncology under the leadership of Dr. Tolcher being an ideal site for the study, enrolling the first patient shortly, PTX-35 being a promising product candidate,PTX-35 providing additional treatment options for patients when current therapy does not work in controlling their cancer and PTX-35 being a potential first-in-class antibody T-cell co-stimulator targeting TNFRSF25. 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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