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NIGHTHAWK BIOSCIENCES

Heat Biologics Announces FDA Clearance of IND Application to Begin Phase 1 Trial of HS-130 in Combination with Heat's HS-110

HS-130 is the first allogeneic, off-the-shelf, cell therapy approach utilizing OX40-mediated co-stimulation to enhance activation of dormant immune signals
Clinical enrollment expected to commence in Q4 2019

DURHAM, NC / ACCESSWIRE / August 12, 2019 / Heat Biologics, Inc. (NASDAQ:HTBX), a clinical-stage biopharmaceutical company specialized in the development of therapeutics designed to activate a patient's immune system against cancer, today announced that the U.S. Food & Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application to initiate a Phase 1 clinical trial of HS-130, in combination with HS-110, for patients with advanced solid tumors refractory to standard of care.

HS-130 is Heat's allogeneic ("off-the-shelf") cell line engineered to express the extracellular domain of OX40 ligand fusion protein (OX40L-Fc), a key costimulator of T cells, with the potential to augment antigen-specific CD8+ T cell response. HS-130 was manufactured by utilizing the Company's proprietary process of reprogramming a live, genetically modified cell line. Improved efficacy and safety were demonstrated in multiple preclinical scenarios using OX40L-Fc via cell-based delivery compared to systemic delivery of an OX40 agonist antibody in combination with HS-110.

"HS-130 represents a major advance in the broad utility and versatility of our T-Cell Activation Platform (*TCAP*)," said Jeff Wolf, Founder & CEO of Heat. "We are leveraging the scientific, clinical and manufacturing expertise that we refined in the development of our HS-110 program in our effort to advance multiple cell-based cancer therapeutics for the activation of patients' immune system. We look forward to providing further updates on both the upcoming trial and clinical enrollment, which we expect to commence in the fourth quarter of 2019."

"HS-130 is the first cell-based approach that utilizes OX40 co-stimulation," said Jeff Hutchins, Ph.D., Heat's Chief Scientific and Operating Officer. "In our first-in-human dose escalation study, we are evaluating the potential synergy of combining HS-130 with HS-110, our NSCLC cell line that secretes up to 90 "neoantigens" combined with gp96, the body's most powerful natural immune adjuvant. Once the optimal dose and ratio of OX40L-Fc and GP96-Fc are confirmed clinically, our future development plan includes engineering a single cell line that secretes both agents."

About T-Cell Activation Platform (*TCAP*)

Heat Biologics' proprietary *TCAP* is an allogenic ("off-the-shelf"), cell-based system. This platform enables the combination of multiple T cell stimulators and/ or activators within a single cell system. Currently HS-110 and HS-130 are in clinical development with engineered gp96-Fc and OX40L-Fc, respectively.

About HS-110

HS-110 is the company's lead product candidate utilizing *TCAP*. This product candidate is designed by engineering gp96-Fc to deliver 78 cancer antigens to stimulate the patients' immune system and activate a robust cytotoxic T cell response. HS-110 is currently being evaluated in a Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®) or with Merck's pembrolizumab (Keytruda®).

About HS-130

HS-130 is a new cell line developed using *TCAP* that is expected to be entering clinical trials in Q4/19. HS-130 is designed to secrete OX40L-Fc, a potent inducer of antigen-specific CD8+ T cell proliferation. The first-in-human study aims to evaluate the safety and dose-response of HS-130 in combination with HS-110 in patients with advanced solid tumors.

About Heat Biologics, Inc.

Heat Biologics is a clinical-stage biopharmaceutical company developing novel therapeutics designed to activate a patient's immune system against cancer using CD8+ "Killer" T-cells. Pelican Therapeutics, Inc., a subsidiary of Heat, is focused on the development of co-stimulatory monoclonal antibody and fusion protein-based therapies designed to activate the immune system. For more information, please visit www.heatbio.com.

Forward Looking Statements

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 regarding the commencement in the fourth quarter of 2019 of clinical enrollment of a Phase 1 Trial of HS-130 in combination with Heat's HS-110, for patients with advanced solid tumors refractory to standard of care, the potential of HS-130 to augment antigen-specific CD8+ T cell response, engineering a single cell line that secretes both OX40L-Fc and GP96-Fc, and the leveraging of Heat's scientific, clinical and manufacturing expertise that was refined in the development of our HS-110 program in an effort to advance multiple cell-based cancer therapeutics for the activation of patients' immune system, *. 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, 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, 2018 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

Fromm G, de Silva S, Giffin L, Xu X, Rose J, Schreiber TH. Gp96-Ig/Costimulator (OX40L, ICOSL, or 4-1BBL) Combination Vaccine Improves T-cell Priming and Enhances Immunity, Memory, and Tumor Elimination. Cancer Immunol Res. 2016 Sep 2;4(9):766-78.

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