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Heat Biologics Announces New PTX-35 Preclinical Data in Organ Transplantation and Provides Update on HS-110

Data demonstrates that PTX-35 may have utility in solid organ transplantation, and to potentially slow or mitigate deleterious immune responses where self-tissue tolerance is impaired

DURHAM, N.C., Jan. 12, 2022 (GLOBE NEWSWIRE) -- **Heat Biologics, Inc. ("Heat") (NASDAQ: HTBX)**, a clinical-stage biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, today announced promising new preclinical data regarding PTX-35 has been accepted for publication in the American Journal of Transplantation and is available at:

<https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16940>.

Key Findings:

- A single dose of the preclinical version of PTX-35 (mPTX-35), was able to expand regulatory T cells (Tregs) and significantly improve disease and graft survival outcomes.
- Chemically induced pancreatic failure (a model for type-1 diabetes) could be partially reversed when mice were transplanted with beta-cell islet allografts and treated with mPTX-35.
- Disease protection in preclinical models was correlated with a significant expansion of Tregs and protection of the allograft, resulting in euglycemia and a graft survival benefit.
- Long-term surviving grafts showed a marked increase in Treg infiltration which directly correlated with mPTX-35 agonist activity.

PTX-35 is a novel, potential first-in-class antibody immunomodulator of TNFRSF25 (death receptor 3), a receptor that is preferentially expressed by antigen-experienced T cells and can be manipulated to expand regulatory T-cell subsets. PTX-35 is the Company's first antibody-based product, currently in a Phase 1 clinical trial for the treatment of patients with solid tumors.

[Dr. James Shapiro](#), Professor in the Department of Surgery and Clinical Islet Transplant Program at the University of Alberta, Edmonton, Canada, commented, "The study demonstrated that a single dose of PTX-35 enabled prolonged graft survival in a mouse model of pancreatic islet allotransplantation. Additionally, PTX-35 could contribute to achieving lasting immunological tolerance in organ transplantation."

Jeff Wolf, Chief Executive Officer of Heat, commented, "We are very encouraged by these

results showing pronounced Treg expansion and significantly prolonged graft survival compared to control. PTX-35 has the potential to modulate immunological responses and may facilitate minimization of post-transplant immunosuppression, which supports further clinical evaluation in the context of inflammatory disease. Similar preclinical results have also been previously demonstrated for bone marrow, corneal and cardiac transplantation using these and other TNFRSF25 agonists.”

Mr. Wolf further noted, “We are also making significant progress with HS-110 and expect to file for an End of Phase 2 meeting with the FDA this quarter. Our goal for this meeting is to discuss potential Phase 3 registration pathways for HS-110. Although this submission is taking longer than expected, we believe we have prepared a very comprehensive package and look forward to the FDA’s feedback.”

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company focused on developing first-in-class therapies and vaccines to modulate the immune system. Heat’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 a Phase 2 trial, various infectious disease/biological threat programs in preclinical development and 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 partially reversing chemically induced pancreatic failure (a model for type-1 diabetes) when mice were transplanted with beta-cell islet allografts and treated with mPTX-35, PTX-35 contributing to achieving lasting immunological tolerance in organ transplantation, the potential of PTX-35 to modulate immunological responses and facilitate minimization or withdrawal of immunosuppression post-transplant, which supports further clinical evaluation in the context of inflammatory disease, expected filing for HS-110 for an End of Phase 2 meeting with the FDA this quarter, and the potential Phase 3 registration pathways for HS-110. 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, Heat's vaccine platform to provide protection against COVID-19, 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 including a Phase 3 registration pathway for HS-110 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.

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