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Heat Biologics and University of Miami Announce Zika Vaccine Collaboration

New Infectious Disease Subsidiary to Apply Heat's Proprietary Platform Technology to Zika Virus and Other Infectious Diseases

Program to Focus on Protecting the Fetus from Zika Transmission

DURHAM, N.C., Oct. 25, 2016 (GLOBE NEWSWIRE) -- Heat Biologics, Inc. (Nasdaq:HTBX), a leader in the development of gp96-based immunotherapies that activate a patient's immune system to fight cancer, announced that it has entered into an agreement with the University of Miami for the license and development of a portfolio of patents leveraging its gp96 platform to target the Zika virus and other infectious diseases. Heat has formed a wholly-owned subsidiary, Zolovax, Inc., to focus on the development of gp96-based vaccines targeting Zika, HIV, West Nile, dengue and yellow fever.

The Zika program emerged from the same laboratory that originally developed Heat's current platform technologies, and will be developed at the University of Miami Miller School of Medicine under the direction of Natasa Strbo, M.D., D.Sc., a reproductive immunologist, who is focused on researching the immune system's interaction with the placenta. Dr. Strbo is also a co-developer of Heat's gp96 platform and has spent many years advancing the platform as a vaccine against malaria and HIV.

Clinical and preclinical studies suggest that Heat's gp96 platform may have a role as a broad-based infectious disease vaccine. Heat has treated more than 200 cancer patients to date with its gp96-based therapeutic vaccines (HS-110 and HS-410), which have induced strong antigen-specific immune response, with an excellent safety profile.

Dr. Strbo and her team have shown that Heat's gp96-based vaccine for SIV (the primate equivalent of HIV) induces a dramatic antigen-specific immune response in the mucous membranes. The treated animals were 73 percent less likely to acquire a particularly virulent form of the SIV virus. These data support broader use of the vaccine in other diseases attacking the mucous membranes and barrier organs, such as the placenta in Zika infection (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3594107).

In the case of Zika, the placenta is believed to play a key role in virus transmission from mother to fetus. Researchers have observed profound pathological changes in Zika-infected placentas, suggesting that the placenta's naturally protective barrier function is impaired during Zika infection. Heat believes that the robust mucosal immune response generated by gp96 in ongoing studies supports the development of a gp96 vaccine that could also stimulate a Zika-specific immune response in the placenta, thus protecting the fetus from virus transmission.

"Miami has become the epicenter for Zika transmission in the U.S.," said Dr. Strbo. "Current

approaches against Zika have not been shown to protect the placenta or transmission of Zika to the fetus. In NIH-funded studies, a gp96-based vaccine effectively protected primates from acquiring the SIV virus and induced T-cells to infiltrate cancer tumors after human vaccination. This led us to hypothesize that a gp96 vaccine might stimulate a similar virus-specific response in the placenta of Zika-infected women that could clear the virus and protect the fetus. We are currently pursuing this approach in our preclinical studies."

"Innovations related to the gp96 platform continue to emerge from the Department of Microbiology and Immunology," said Norma Kenyon, Ph.D., Vice Provost for Research at the University of Miami and Chief Innovation Officer at the Miller School of Medicine. "Dan Catron, Senior Licensing Associate in the Office of Technology Transfer, worked with Dr. Strbo and Heat to accelerate the path toward development and commercialization via licensing of this technology, resulting in the formation of a new UM startup. This is expected to lead to more rapid development and testing of vaccines that can ameliorate Zika and other infectious diseases."

"We are excited about our collaboration with the University of Miami to develop a gp96-based vaccine designed to prevent the spread of Zika and protect the fetuses of women who contract it," said Jeff Wolf, CEO of Heat Biologics. "Gp96-Ig is a powerful vaccine platform that has been shown to induce a potent and localized immune response and mucosal immunity, which may protect against Zika and other infectious diseases. Zolovax, our newly formed subsidiary, will focus exclusively on developing gp96-based vaccines for infectious diseases, and we are actively pursuing additional collaborative research partners to complement these efforts."

About Heat Biologics, Inc.

Heat Biologics, Inc. (Nasdaq:HTBX) is an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer utilizing an engineered form of gp96, a protein that activates the immune system when cells die. Heat's highly specific T cell-stimulating therapeutic vaccine platform technologies, *ImPACT* and *ComPACT*, form the basis of its product candidates. These platforms, in combination with other therapies, such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms of action: robust activation of CD8+ "killer" T cells (one of the human immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance patients' immune response. Currently, Heat is conducting a Phase 2 trial with its HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC) and a Phase 1b trial with its HS-110 (viagenpumatucel-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC). For more information, please visit www.heatbio.com.

About Zolovax, Inc.

Zolovax Inc. is developing therapeutic and preventative vaccines to treat infectious diseases based on gp96 vaccine technology. Zolovax is currently focused on vaccines targeting the Zika virus and HIV, and has a patent portfolio that also includes West Nile virus, Dengue and yellow fever. Zolovax is a wholly-owned subsidiary of Heat Biologics.

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, expectations and assumptions and include statements regarding the suggestion that Heat's gp96 platform may have a role as a broad-based infectious disease vaccine, the belief that in Zika the placenta plays a key role in virus transmission from mother to fetus, the potential use of gp96 as a vaccine for diseases attacking the mucous membranes and barrier organs, such as the placenta in Zika infection, the suggestion that the placenta's naturally protective barrier function is impaired during Zika infection and the belief that the mucosal immune response generated by gp96 in ongoing studies, supports the development of a gp96 vaccine that could also stimulate a Zika-specific immune response in the placenta, protecting the fetus from virus transmission, the hypothesis that a gp96 vaccine might stimulate a similar virus-specific response in the placenta of Zika-infected women that could clear the virus and protect the fetus, the expectation that the new UM start-up will ultimately lead to more rapid development and testing of vaccines that can ameliorate Zika and other infectious disease and the potential of Heat's *ImPACT* and *ComPACT* therapies. These statements are based on management's expectations and assumptions as of the date of this press release and are subject to a number of risks and uncertainties, many of which are difficult to predict that could cause actual results to differ materially from current expectations and assumptions from those set forth or implied by any forward-looking statements, including the ability of Heat's *ImPACT* and *ComPACT* therapies and any gp96 vaccine developed to treat Zika 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, the company's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to the company'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, the company'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, and its ability to retain its key scientists or management personnel and the other factors described in the company's annual report on Form 10-K for the year ended December 31, 2015 and other filings with the SEC. The information in this release is provided only as of the date of this release and the company 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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