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Heat Biologics' Pelican Subsidiary Provides Update on its Novel PTX-35 T-Cell Costimulator

PTX-35 Featured in Nature Publication

DURHAM, NC / ACCESSWIRE / October 4, 2018 /[Heat Biologics, Inc.](#) (NASDAQ: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, and its Pelican Therapeutics subsidiary ("Pelican") today provided a progress update on its novel PTX-35 co-stimulatory antibody. PTX-35 is designed to harness the body's natural antigen-specific immune activation mechanisms. When combined with immunotherapies, including checkpoint inhibitors as well as Heat's *ImPACT*® and *ComPACT*™ technologies, PTX-35 has been shown to enhance antigen-specific T-cell activation to eliminate tumor cells in pre-clinical models.

Recent PTX-35 highlights:

- Completed cell line development and creation of validated master cell bank for cGMP manufacturing
- Established CMC path for the production of GMP clinical material and non-clinical preliminary pharmacology / non-GLP toxicology studies
- Preliminary non-GLP pharmacology demonstrates positive results, including efficient binding and activation on cells expressing the TNFRSF25 receptor, as well as increased expansion of T-cells in-vivo
- 2-week IND enabling dose range finding toxicology studies in primates receiving two doses show no signs or signals of clinical toxicity across wide dose range
- Ongoing pre-IND discussions with FDA; expect to submit IND in Q1 2019

Rahul Jasuja, Ph.D., CEO of Pelican, commented, "We are progressing rapidly with our pre-clinical activities and expect to submit an IND for PTX-35 in the first quarter of 2019. We are strongly encouraged by the preliminary pre-clinical efficacy and safety data which shows no signs of toxicity across a wide range of doses."

Dr. Jasuja continued, "We have been efficient in our use of funds, which has allowed us to come in under budget, further extending our runway for this program. Given our operating efficiency thus far, we expect to receive the next tranche of grant funding once we fully utilize the funds that the Cancer Prevention Research Institute of Texas ("CPRIT") has previously provided. As we progress, our plan is to advance a broad clinical development program that could include combination therapy with Heat's *ImPACT*® and *ComPACT*™

therapies, as well as other costimulatory agonists, checkpoint inhibitors and immune modifiers to address the unmet need for patients who do not respond well to current cancer therapies."

The Company further reported that PTX-35 was featured in Nature's Biopharma Dealmakers September 2018 edition, which is available at: https://heatbio.com/wp-content/uploads/2018/09/Activating_Antitumor_Activity-Nature_Biopharma_Sept-2018.pdf

To-date, Pelican has received \$8.3 million in grants from CPRIT. The CPRIT award supports pre-clinical development, manufacturing and clinical development through a comprehensive 70-patient Phase 1 clinical trial for PTX-35. The Company expects to meet the qualifications to receive the third tranche of its \$15.2 million CPRIT grant award, totaling \$6.9 million, later this year.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer using of CD8+ "Killer" T-cells. Our T-Cell Activation Platform (TCAP) produces therapies designed to turn "cold" tumors "hot" and be administered in combination with checkpoint therapies and other immuno-modulators to increase their effectiveness. HS-110 is our first biologic product candidate in a series of proprietary immunotherapies designed to stimulate a patient's own T-cells to attack cancer. Our *ComPACT*[™] technology is the first potential, dual-acting immunotherapy designed to deliver T-cell activation and co-stimulation in a single product. We are currently enrolling patients in our Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®). We also have numerous pre-clinical programs at various stages of development. For more information, please visit www.heatbio.com.

About Pelican Therapeutics

Pelican Therapeutics, Inc., a subsidiary of Heat, is focused on the development of therapies designed to activate the immune system. PTX-35 targets the T-cell co-stimulator, TNFRSF25, and is designed to harness natural immune mechanisms that may reprogram tumor immunity. When combined with immunotherapies, including Heat's T-cell Activation Platform (TCAP), PTX-35 may have the ability to boost antigen-specific T-cells and eliminate tumor cells in patients.

In June 2016, Pelican was awarded a \$15.2 million Cancer Prevention Institute of Texas (CPRIT) grant to support further development of PTX-35 and fund a Phase 1 clinical trial to examine potential benefits to patients with several types of cancers.

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 expected filing

of an IND for PTX-35 in the first quarter of 2019, the expected receipt of funding from CPRIT, the ability of PTX-35 to harness the body's natural antigen-specific immune activation mechanisms, to boost antigen-specific T-cells and eliminate tumor cells in patients, and the plan to advance a broad clinical development program that could include combination therapy with ImPACT® and ComPACT™, as well as other costimulatory agonists, checkpoint inhibitors and immune modifiers to address the unmet need for patients who don't respond well to current cancer 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® therapy, ComPACT™ therapy and PTX-35 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 ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Heat's and Pelican's ability to promote or commercialize product candidates for specific indications, acceptance of product candidates in the marketplace and the successful development, marketing or sale of products, the ability to maintain license agreements, the continued maintenance and growth of the patent estates, the ability to establish and maintain collaborations, the ability to obtain or maintain the capital or grants necessary to fund its research and development activities, and the ability to retain key scientists or management personnel, and the other factors described in Heat's most recent annual report on Form 10-K 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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