December 7, 2017

Heat Biologics Receives FDA Guidance at Type C Meeting for HS-110 Clinical Trial in the Treatment of Non-small Cell Lung Cancer

DURHAM, NC / ACCESSWIRE / December 7, 2017 /Heat Biologics, Inc. ("Heat") (NASDAQ: HTBX), a biopharmaceutical company developing drugs designed to activate a patient's immune system against cancer, received written responses from the U.S. Food and Drug Administration (FDA) following its Type C meeting regarding its planned registrational HS-110 clinical trial design for the treatment of non-small cell lung cancer (NSCLC).

The discussion focused on elements of proposed clinical trial designs, both single-arm and controlled, which the FDA agreed would be appropriate to support a registrational trial of HS-110. Clinical endpoints and post-marketing commitments were also discussed in the context of accelerated approval.

"We are very pleased with the outcome of our recent Type C guidance meeting with the FDA," said George Peoples, M.D., Chief Medical Officer for Heat. "The FDA clearly understands the significant unmet need for more effective second-line treatments for NSCLC. We look forward to incorporating their guidance as we prepare to advance HS-110 into registrational trials."

HS-110 is currently in Phase 2 as a treatment for NSCLC. Trial design details and next steps are expected to be announced following the read-out of the Phase 2 data, anticipated in 2H 2018.

About Heat Biologics, Inc.

Heat Biologics is a biopharmaceutical company developing immunotherapies designed to activate a patient's immune system against cancer by inducing 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 inhibitor therapies and other immuno-modulators to increase their effectiveness. We are currently enrolling patients in our Phase 2 clinical trial for non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®). Pelican Therapeutics, 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. We also have numerous pre-clinical programs at various stages of development. 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, expectations and assumptions and include statements regarding the expected announcement of the trial design and next steps, the anticipated timing of the read-out of the Phase 2 data and the potential benefits of our products. 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 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, and its ability to retain its key scientists or management personnel, its ability to successfully integrate Pelican, the successful completion of the rights offering 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.

Contacts

Media and Investor Inquiries
Melissa Conger
Heat Biologics
+1 919 289 4017
mconger@heatbio.com