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Heat Biologics Completes Enrollment in Phase 2 Non-Small Cell Lung Cancer Trial

DURHAM, NC / ACCESSWIRE / July 9, 2019 / Heat Biologics, Inc. (NASDAQ: HTBX), a biopharmaceutical company developing therapies designed to activate a patient's immune system against cancer, today announced it has completed recruitment for enrollment in its Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®) or Merck's pembrolizumab (Keytruda®). In total, approximately 120 patients have been enrolled in the trial.

Lori McDermott, Heat's VP of Clinical Development, said, "We are pleased to report that our Phase 2 enrollment targets were achieved on schedule. Last month, we reported promising interim results from the study showing that the addition of HS-110 to nivolumab may restore anti-tumor activity in patients whose disease has progressed after checkpoint inhibitor therapy. These results continue to support our mechanistic hypothesis that the broad, T-cell mediated immune response activated by HS-110 may improve clinical outcomes for those patients who are least likely to respond to a checkpoint inhibitor, including those whose disease has worsened during or after checkpoint inhibitor therapy."

Jeff Wolf, Heat's CEO, commented, "We are pleased to achieve this important milestone and delighted with the patient mix which includes those whose disease has progressed after prior checkpoint inhibitor treatment failure. We look forward to reporting additional results 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 have reached the enrollment targets in our Phase 2 clinical trial for advanced non-small cell lung cancer, in combination with Bristol-Myers Squibb's nivolumab (Opdivo®) and with Merck's pembrolizumab (Keytruda®), and expect to report additional results before the end of 2019. 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 that the addition of HS-110 to nivolumab may restore anti-tumor activity in patients whose disease has progressed after checkpoint inhibitor therapy, that the results continue to support our mechanistic hypothesis that the broad, T-cell mediated immune response activated by HS-110 may improve clinical outcomes for those patients who are least likely to respond to a checkpoint inhibitor, including those whose disease has worsened during or after checkpoint inhibitor therapy and the reporting of additional results before the end of 2019. 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 and otherfilings 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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