June 3, 2019

Heat Biologics Announces Promising Interim Phase 2 Lung Cancer Data Suggesting that HS-110 Plus Nivolumab May Restore Clinical Benefit After Checkpoint Inhibitor Treatment Failure

Clinical benefit observed in 55% of patients receiving HS-110 plus nivolumab after checkpoint inhibitor treatment failure

HS-110 in combination with nivolumab demonstrates clinical activity in low CD8+ TIL "cold tumor" patients and PD-L1 negative tumors

The occurrence of dermal injection site reactions is associated with improved progression free survival (p=0.013) and overall survival (p=0.002)

Cohort B results presented yesterday at the 2019 ASCO Annual Meeting poster session

DURHAM, NC – – June 3, 2019 – Heat Biologics, Inc. (NASDAQ: HTBX), a biopharmaceutical company developing therapies designed to activate a patient's immune system against cancer, today announced compelling new interim results from its ongoing Phase 2 study investigating HS-110 in combination with Bristol-Myers Squibb's anti-PD-1 checkpoint inhibitor, nivolumab (Opdivo®). The updated results were obtained from Cohort B patients whose data has matured an additional 3 months since last reported at the ASCO-SITC Clinical Immuno-Oncology Symposium in February of this year. This data may represent the first Phase 2 data showing clinical activity in non-small cell lung cancer (NSCLC) patients whose disease has progressed after prior treatment with a checkpoint inhibitor (CPI). The Cohort B results were presented yesterday at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting poster session.

COL(ret) George E Peoples, MD, FACS, Heat's Chief Medical Advisor, noted, "These latest Cohort B data provides us even greater confidence that the addition of HS-110 to nivolumab may restore anti-tumor activity in patients whose disease has progressed after treatment with a CPI. Of particular note, 4 out of 5 evaluable patients in Cohort B with PD-L1 negative tumors achieved disease stabilization and 4 out of 7 evaluable patients with low CD8+ TIL levels in their tumors achieved disease stabilization. We are encouraged by these positive results and look forward to reporting additional data later this year."

Jeff Hutchins, Ph.D., Heat's Chief Scientific and Operating Officer said, "The fact that we saw tumor shrinkage in 35% of patients and disease control in 55% of patients whose disease has progressed after treatment with a CPI supports our mechanistic hypothesis that the broad, T-cell mediated immune response activated by HS-110 may improve clinical outcomes for patients who have lost the benefit of treatment with a checkpoint inhibitor. It is also important to note that the occurrence of dermal injection site reactions is associated with statistically significant improved progression free survival and overall survival, providing further support for the mechanism of action of HS-110."

Highlights for Cohort B patients are presented below:

- HS-110 in combination with nivolumab demonstrates clinical activity in 'difficult to treat' low CD8+ TIL (≤10%) and PD-L1 negative (<1%) tumors:
  - 4 out of 5 evaluable patients with PD-L1 negative tumors achieved disease stabilization, 1 of which was a RECIST partial response.
  - 4 out of 7 evaluable patients with low CD8+ TIL tumors achieved disease stabilization, 2 of which were RECIST partial responses.
- The addition of HS-110 to nivolumab may restore clinical benefit to patients whose disease has progressed after CPI treatment failure:
  - Tumor shrinkage observed in 35% of patients
  - Disease control rate of 55%
  - Median Progression-Free Survival (mPFS) of 2.7 months
  - Median Overall Survival (mOS) not yet reached
- The occurrence of any grade dermal Injection Site Reaction during treatment (Y/N) is associated with improved Progression-Free Survival and Overall Survival:
  - mPFS: NR vs 1.8 months; HR 0.17 (95% CI, 0.03-0.84);*p=0.013*
  - mOS: NR vs 5 months; HR 0.13 (95% CI, 0.02-0.71);*p=0.002*

Treatment with HS-110 in combination with nivolumab was well tolerated, with no additional toxicities beyond those observed with single agent CPI therapy.

Trial results are summarized in the official2019 ASCO Annual Meeting poster.

Trial Design

The Phase 2 trial is designed to evaluate the safety and efficacy of HS-110 combined with an immune checkpoint inhibitor for the treatment of advanced non-small cell lung cancer. Cohort B consists of patients who received a minimum of 4 months of treatment with a checkpoint inhibitor (CPI) as part of their prior therapy, but subsequently had documented progressive disease. Patients receive weekly HS-110 (1×10^7 cells) administered as 5 intradermal 0.1 mL injections for 18 weeks in combination with bi-weekly nivolumab 240 mg IV administered until confirmed disease progression or unacceptable toxicity, whichever occurs first. The primary endpoint is objective response rate (ORR); secondary endpoints include overall survival (OS), progression-free survival (PFS), disease control rate (DCR) and duration of response (DOR). Exploratory endpoints include correlation of clinical outcomes to baseline CD8+ TILs, PD-L1 expression, peripheral blood tumor mutation burden and ELISPOT analysis.

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®) and with Merck's pembrolizumab (Keytruda®). 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 data may represent the first Phase 2 data showing clinical efficacy for non-small cell lung cancer patients whose disease has progressed after treatment with a checkpoint inhibitor (CPI), that the addition of HS-110 to nivolumab may restore anti-tumor activity in patients whose disease has progressed after treatment with a CPI, that the broad, T-cell mediated immune response activated by HS-110 may improve clinical outcomes for patients who have lost the benefit of treatment with a checkpoint inhibitor and the ability of Heat's T-Cell Activation Platform to produce therapies designed to turn "cold" tumors "hot" and to increase their effectiveness of checkpoint therapies and other immuno-modulators. 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, and its ability to retain its key scientists or management personnel, and the other factors described in Heat's 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.

Media and Investor Relations Contact
David Waldman

+1 919 289 4017
investorrelations@heatbio.com

SOURCE: Heat Biologics, Inc.

View source version on accesswire.com:
https://www.accesswire.com/547417/Heat-Biologics-Announces-Promising-Interim-Phase-2-Lung-Cancer-Data-Suggesting-that-HS-110-Plus-Nivolumab-May-Restore-Clinical-Benefit-After-Checkpoint-Inhibitor-Treatment-Failure