September 1, 2015

Heat Biologics Announces Clinical Trial Combining HS-110 and PD-1 Checkpoint Inhibitor in NSCLC

Checkpoint Combination Trial to Replace Existing Trial in New Treatment Landscape; Timelines to Registration-Directed Study Remain Unchanged

Conference Call and Webcast Today at 8:30 AM EDT

DURHAM, N.C., Sept. 1, 2015 (GLOBE NEWSWIRE) --Heat Biologics, Inc. (NASDAQ:HTBX), a clinical stage cancer immunotherapy company, announced that it has enrolled the first patient in a Phase 1b clinical trial investigating the combination of its HS-110 therapeutic vaccine and the Bristol-Myers Squibb PD-1 inhibitor nivolumab (Opdivo®) in non-small cell lung cancer (NSCLC). HS-110 is the Company's first product candidate in a series of proprietary *ImPACT*™ based immunotherapies designed to stimulate patient's own T-cells to attack cancer. Additionally, as the FDA approval of nivolumab and anticipated approval of other checkpoint inhibitors is dramatically changing the standard of care in lung cancer treatment, Heat is winding down its ongoing Phase 2 trial with HS-110, which does not include a checkpoint inhibitor combination, to instead focus on combinations with checkpoint inhibitors.

This multicenter trial is evaluating the safety and efficacy of HS-110 in combination with nivolumab in patients with NSCLC whose cancers have progressed after first-line therapy. Primary and secondary trial endpoints include safety and tolerability, immune response, overall response rate and progression-free survival.

"Checkpoint inhibitors such as nivolumab are rapidly becoming standard of care in the treatment of NSCLC and many other types of cancer," stated Jeff Wolf, CEO of Heat Biologics. "Substantial evidence is emerging regarding the benefits of combining checkpoint inhibitors and therapeutic vaccines. Heat had previously reported synergy between *ImPACT* and anti-PD-1 therapy. This important clinical study is among the first trials to explore the combination of a checkpoint inhibitor and therapeutic vaccine in NSCLC and will enable us to more fully evaluate this combination with other checkpoint inhibitors, such as Merck's pembrolizumab, as they become available."

"We reported earlier this year, in a clinical trial for HS-410 for bladder cancer, that patients with low levels of tumor-infiltrating lymphocytes (TILs) at baseline appeared to respond better," said Taylor Schreiber, M.D., Ph.D., Heat's Chief Scientific Officer. "This is consistent with emerging clinical evidence demonstrating that while responses to checkpoint inhibitor therapy are biased toward patients with pre-existing TILs, the optimal patient population for therapeutic vaccines in conjunction with checkpoint inhibitors may in fact be the checkpoint unresponsive (and TIL negative) population. Currently, only 20% to 30% of NSCLC patients

respond to nivolumab. This trial will specifically investigate whether HS-110can broaden the base of patients who respond to nivolumab and other checkpoint inhibitors."

"This trial is expected to initially enroll 18 patients, and is designed to accommodate rapid cohort expansion as positive clinical data emerge," stated Melissa Price, Ph.D., Heat's VP of Product Development. "We will be working with Yale Cancer Center's Translational Immuno-Oncology Laboratory on the analysis of the TILs biomarker data for patient selection. We expect to release top-line objective response rate and 6-month progression free survival (PFS) data on these first 18 patients by the end of 2016, which should enable us to reach a clinical readout for HS-110 with a checkpoint-focused clinical trial, on the same schedule that we had forecasted for our previous trial. Our expectations around the timing of an HS-110 registration-directed study in NSCLC remain unchanged."

Nivolumab (Opdivo) was approved by the US Food and Drug Administration (FDA) for the treatment of NSCLC in March 2015 and is marketed by Bristol-Myers Squibb. Another anti-PD-1 drug candidate, Merck's pembrolizumab (KEYTRUDA®) is currently under FDA Priority Review for NSCLC.

Conference Call

Tuesday, September 1, 2015 @ 8:30am Eastern Time

Toll Free:	888-572-7025
International:	719-457-2085
Conference ID:	9960179
Webcast and slides:	http://ir.heatbio.com/events-presentations

Replays *(Available through September 15, 2015):*

Toll Free:	877-870-5176
International:	858-384-5517
Conference ID:	9960179

About the Trial

The trial is an ongoing multicenter, open label Phase 1b trial evaluating the safety and efficacy of HS-110 in patients with non-small cell lung cancer patients who have failed at least one other therapy. The trial is designed to evaluate HS-110 in combination with multiple tumor anti-immunosuppressive and checkpoint agents through a single protocol. In one arm, patients with low baseline TIL expression will receive HS-110 plus nivolumab. In another arm, patients with a high baseline TIL expression will receive HS-110 plus nivolumab.

About Viagenpumatucel-L (HS-110)

Viagenpumatucel-L (HS-110) ImPACT-modified cell lines are designed to stimulate a patient's immune system to activate a cytotoxic T-cell response against a range of antigens known to be expressed by a high proportion of patients with non-small cell lung cancer (NSCLC). The backbone cell line for HS-110 was selected based on overlapping antigen expression in patient tumor specimens, including known and unknown antigens, and functions dually as an antigen delivery vehicle and adjuvant, to stimulate the immune system. By addressing the underlying genetic and antigenic heterogeneity within tumors,

ImPACT vaccines can potentially treat all patients, a significant advantage over single antigen therapies.

About Heat Biologics, Inc.

Heat Biologics, Inc. (www.heatbio.com) is a clinical-stage biopharmaceutical company focused on developing novel, "off-the-shelf" *ImPACT*™ and *ComPACT* platform based therapeutic vaccines to combat a wide range of cancers. Our *ImPACT*™ Therapy is designed to deliver live, genetically-modified, irradiated human cells that are reprogrammed to "pump out" a broad spectrum of cancer-associated antigens delivered via a potent immune adjuvant, gp96, to activate a cancer patient's immune system to recognize and kill cancerous cells. *ComPACT* Therapy is designed to deliver T-cell priming and co-stimulatory molecule in a single product. Heat is conducting a Phase 1b trial of its viagenpumatucel-L (HS-110) cancer vaccine in patients with non-small cell lung cancer in combination with checkpoint inhibitors and a Phase 2 trial with its vesigenurtacel-L (HS-410) in patients with non-muscle invasive bladder cancer.

Forward Looking Statements

This press release includes forward-looking statements 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 timing of enrollment, the number of patients to be enrolled, the expected release of top-line response rate and PFS data, the timing of an HS-110 registration-directed study in NSCLC and the potential of the *ImPACT* vaccines. These statements are subject to a number of risks and uncertainties, many of which are difficult to predict, including the ability for Heat's *ImPACT*™ Therapy to perform as designed, the ability to timely enroll patients and complete the clinical trial on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2014 and Heat's other filings with the SEC. The information in this release is provided only as of the date of this release, and we undertake 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.

Opdivo® is a registered trade mark of Bristol-Myers Squibb. KEYTRUDA® is a registered trademark of Merck & Co., Inc.

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Source: Heat Biologics