

September 18, 2014



Heat Biologics Commences Patient Dosing in Phase 2 Study of Viagenpumatulcel-L for the Treatment of Non-Small Cell Lung Cancer

Clinical Trial Protocol Designed to Demonstrate Improved Overall Survival With Combination Immunotherapy

DURHAM, N.C., Sept. 18, 2014 (GLOBE NEWSWIRE) --[Heat Biologics, Inc.](#) ("Heat Biologics", "Heat" or the "Company") (Nasdaq:HTBX), a clinical stage biopharmaceutical company focused on the development of cancer immunotherapies, announced today that it has initiated dosing in its Phase 2 trial of Viagenpumatulcel-L ([HS-110](#)) in patients with non-small cell lung cancer ("NSCLC"). HS-110 is Heat's most advanced product candidate in a series of proprietary Immune Pan Antigen Cytotoxic Therapy ("[ImPACT](#)") based allogeneic cell lines designed to direct killer T cells to attack cancer. Roger B. Cohen, M.D., Professor of Medicine at the University of Pennsylvania and Associate Director for Clinical Research for the Abramson Cancer Center is Lead Investigator of the Phase 2 trial.

Dr. Cohen commented, "NSCLC is still the most common lethal cancer. The unmet need in this disease is huge. Recent encouraging data with various immune checkpoint inhibitors suggest that NSCLC may, in fact, be susceptible to an immune therapy approach. Heat's biologic immuno-oncology product candidate, HS-110, has a novel composition and mechanism of action that builds on decades of immunotherapy research. I look forward to seeing the effects of HS-110 on immune response and outcome in my patients."

The multicenter, randomized Phase 2 trial will enroll approximately 123 patients with NSCLC who have failed two or three prior lines of therapy. The clinical study will evaluate the safety and efficacy of HS-110 in combination with low-dose cyclophosphamide. The Phase 2 protocol is specifically designed using low-dose cyclophosphamide as a modulator of immunosuppression which is expected to enhance the encouraging signals of efficacy observed in the Phase 1 trial of HS-110 as a monotherapy.

After 14 patients have been treated for nine weeks with Viagenpumatulcel-L and cyclophosphamide, an interim analysis of the immune response data will be conducted. The Company expects to report these interim immune response results in the first half of 2015.

"Dosing the first patients with HS-110 in our NSCLC Phase 2 study is an exciting and significant milestone for the Company," said Jeff Wolf, Chief Executive Officer of Heat. "Our Phase 2 lung cancer study is designed to gauge the effectiveness of our approach in late stage NSCLC patients in a controlled setting, allowing us to design pivotal trials more effectively."

During the trial, immune response and a large group of experimental endpoints will be correlated with patient outcomes with the goal of achieving proof of concept and identifying patients who are most likely to benefit from HS-110.

About Viagenpumatucl-L ([HS-110](#))

Viagenpumatucl-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 that are known to be expressed by a high proportion of patients with NSCLC. The backbone cell line for HS-110 was selected based on antigenic overlap with patient tumor specimens, including known antigens such as MAGE-A3 and NY-ESO-1 as well as approximately a dozen additional known and unknown antigens. This approach is expected to provide a significant advantage over single antigen approaches by reducing the risk of antigen-loss variants emerging post-treatment and by addressing the underlying genetic and antigenic heterogeneity within tumors. Heat Biologics is in Phase 2 clinical trials using HS-110 for the treatment of NSCLC. For more information reference study protocol [NCT02117024](#) on [clinicaltrials.gov](#).

About Heat Biologics, Inc.

Heat Biologics, Inc. ([www.heatbio.com](#)) is a clinical-stage biopharmaceutical company focused on developing its novel, "off-the-shelf" *ImPACT* therapeutic vaccines to combat a wide range of cancers. Our *ImPACT* Therapy is designed to deliver live, genetically-modified, irradiated human cells which are reprogrammed to "pump out" a broad spectrum of cancer-associated antigens together with a potent immune adjuvant called "gp96" to educate and activate a cancer patient's immune system to recognize and kill cancerous cells. Heat's Viagenpumatucl-L ([HS-110](#)) will be entering Phase 2 trials against non-small cell lung cancer and its Vesigenurtacel-L ([HS-410](#)) is being evaluated in an ongoing Phase 1/2 clinical trial against 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 potential for Heat's *ImPACT* Therapy, the use of low-dose cyclophosphamide as a modulator of immunosuppression which is expected to enhance the efficacy observed in the Phase 1 trial of HS-110 as a monotherapy, the expected timing of the report of the interim immune response results, the expected achievements from the trial immune response and, the suggested impact of immune checkpoint inhibitors on NSCLC. 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 of additional checkpoint inhibitors to receive approval and have the impact that is anticipated and ability to enroll patients as planned, and the other factors described in our annual report on Form 10-K for the year ended December 31, 2013 and our 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.

CONTACT: Heat Biologics, Inc. Contact Information:

Matthew Czajkowski
Chief Financial Officer
(919) 240 7133
matt@heatbio.com

Jenene Thomas
Investor Relations and Corporate Communications Advisor
Jenene Thomas Communications, LLC
(908) 938-1475
investorrelations@heatbio.com

Source: Heat Biologics