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Heat Biologics, Inc. Reports 2014 Second Quarter Financial Results

Recent Key Clinical Development Strategy Advancement Accelerates Timeline to Data Readout for Phase 1/2 Bladder Cancer Study

DURHAM, N.C., Aug. 14, 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 its financial results for the second quarter ended June 30, 2014 and outlined key highlights of its lead clinical development programs.

CLINICAL DEVELOPMENT PROGRAM HIGHLIGHTS:

Vesigenurtacel-L (HS-410) for the treatment of bladder cancer

- Reported encouraging preliminary Phase 1 safety data with no serious adverse events for the first seven (7) patients treated in the [Vesigenurtacel-L](#) Phase 1/2 trial;
- Amended HS-410 Phase 1/2 protocol for a more robust dose-response analysis and to expedite the bladder cancer trial directly into Phase 2 in the fourth quarter of 2014;
- Patient enrollment and dosing expected to be completed in the third quarter of 2015; and
- Following a twelve-month observation period of all patients in the trial, top-line results of Phase 1/2 expected to be reported in the third quarter of 2016.

Viagenpumatucl-L (HS-110) for the treatment of non-small cell lung cancer

- Opened two clinical investigational sites for [Viagenpumatucl-L](#) Phase 2 trial;
- Initiated patient screening for enrollment for Viagenpumatucl-L Phase 2 trial; and
- Patient dosing of Phase 2 trial expected to commence late third quarter 2014.

"I firmly believe the core fundamentals of Heat have never been stronger. During the second quarter the team continued to work closely with our renowned [Clinical Advisory Board](#) and principal investigators to progress our two clinical trials. I am very pleased with the substantial progress we are making. Specifically, the recent protocol amendment that we submitted to the FDA and are now implementing for our Phase 1/2 bladder cancer study has the potential to optimize patient outcomes to produce more meaningful safety and efficacy results more rapidly. Our team remains committed to operational excellence, and I believe the achievement of our expected clinical milestones will have the potential to drive substantial shareholder value in the next 12-18 months," stated Jeff Wolf, Heat's Chief Executive Officer.

SECOND QUARTER 2014 FINANCIAL SNAPSHOT

As of June 30, 2014, cash, cash equivalents and short term investments totaled \$16.8 million. Based on Management's projections, the Company's current cash position is anticipated to continue to fund operations for at least the next twelve months.

For the second quarter ended June 30, 2014, Heat Biologics reported a net loss of (\$2,958,357) and a net loss attributable to common stockholders of (\$2,846,915), or (\$0.44) per share as compared to a net loss of (\$1,674,215) and a net loss attributable to common stockholders of (\$1,620,774), or (\$0.92) per share for the second quarter ended June 30, 2013. The increase in the loss was primarily attributable to an increase of \$160,380 in Research and Development expense, an increase of \$658,252 in Clinical and Regulatory expense and an increase of \$576,708 in General and Administrative expense. The components of the increase in expenses are as follows:

The increase in Research and Development spending of \$160,380 from the quarter ending June 30, 2013 to the quarter ending June 30, 2014 is attributable to an increase in compensation expense for Company research and development staff of \$108,229, of which \$38,820 was non-cash, stock-based compensation. Additionally, the Company spent \$70,758 more on patent and license costs in the second quarter of 2014 compared to the second quarter of 2013. The Company incurred \$99,628 in research and development expenses in the second quarter of 2014 establishing a lab facility in Durham, North Carolina. Travel expense for research and development staff was \$9,289 higher in the second quarter of 2014 than the second quarter of 2013. These increases are offset by a decrease of \$168,183 in pre-manufacturing costs as the Company begins manufacturing clinical trial batches. The remaining \$40,659 change is attributable to changes in various other expenses.

The increase of \$658,252 in Clinical and Regulatory expenses from the quarter ending June 30, 2013 to the quarter ending June 30, 2014 is attributable to increases in clinical trial execution costs of \$586,426, as well as increased manufacturing and drug handling costs of \$110,540 related to the production of vaccines for our clinical trials. Personnel cost, including travel, increased by \$113,542 of which \$36,113 was non-cash stock-based compensation. These increases are offset by a decrease of \$144,916 in consulting costs as the Company used employees rather than external consultants. The remaining \$7,340 decrease is attributable to changes in various other expenses.

The \$576,708 increase in General and Administrative expense from the second quarter of 2013 to the second quarter of 2014 is attributable to an increase of \$188,301 related to public company expenses which include professional services such as accountants and attorneys. Additionally, personnel costs increased by \$208,008 from the quarter ending June 30, 2013 to the quarter ending June 30, 2014, of which \$110,171 was non-cash, stock-based compensation. The remainder of the increase in personnel costs is related to hiring. Insurance costs increased by \$91,444 due to the increased risk management requirements of a public company, particularly directors and officers insurance. Additionally, travel and facilities costs increased by \$22,606 and \$10,940, respectively, from the second quarter 2013 to the second quarter 2014. The remaining \$55,409 change is attributable to general and administrative costs such as office expenses, fees, and other miscellaneous administrative costs.

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 Viagenpumatulcel-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 anticipated benefits of the redesigned study, the expected commencement date of dosing of patients in the Phase 2 trial, the expected date of enrollment and dosing for the Phase 1/2 trial, the potential drive in shareholder value, expected date of release of top-line results and the potential for Heat's *ImPACT* Therapy. 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 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.

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