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Heat Biologics, Inc. Reports 2014 First Quarter Financial Results

Lead Immunotherapy Vaccine Product Candidates HS-110 Phase 2 Lung Cancer and HS-410 Phase 1/2 Bladder Cancer Clinical Programs Advancing Through the Clinic

DURHAM, NC -- (Marketwired) -- 05/13/14 -- [Heat Biologics, Inc.](#) ("Heat Biologics", "Heat" or the "Company") (NASDAQ: HTBX), a clinical stage biopharmaceutical company focused on the development of novel cancer immunotherapies, announced today its financial results for the first quarter ended March 31, 2014 and provided highlights of the Company's recent corporate progress and anticipated near-term milestones for its two lead product candidates, [HS-110](#) (Viagenpumatulcel-L) for the treatment of non-small cell lung cancer (NSCLC) and [HS-410](#) (Vesigenurtacel-L) for the treatment of bladder cancer.

"The first quarter was marked by the achievement of significant company milestones. Despite this, we believe that our current share price, which gives us a total enterprise value of under \$10 million, does not reflect this progress, our clinical pipeline or the potential of our immunotherapy platform to treat a variety of different cancers. Heat is focused on the development of a truly breakthrough technology platform with multiple ongoing clinical programs. Our Phase 1/2 clinical study in bladder cancer is well underway, and we are preparing to begin patient enrollment of our Phase 2 study in lung cancer, both areas where we believe we can address unmet medical needs. Our published studies show that Heat's proprietary platform may be an excellent complement for the myriad of checkpoint inhibitors and immune stimulators currently in the clinic. With continued progress, we believe there is room for substantial shareholder growth from our currently depressed market capitalization as we continue to meet our clinical milestones," said Jeff Wolf, Chief Executive Officer of Heat Biologics.

FIRST QUARTER HIGHLIGHTS

- Formed a Clinical Advisory Board of preeminent immunotherapy and oncology leaders with Justin Stebbing, M.D., Ph.D., serving as Chairman and Chief Medical Advisor;
- Commenced enrollment and dosing for Phase 1/2 clinical study of HS-410 for treatment of bladder cancer;
- Appointed oncology immunotherapy expert, Taylor H. Schreiber, M.D., Ph.D., as Vice President of Research and Development;
- Submitted revised protocol for Phase 2 clinical study of HS-110 for treatment of NSCLC to U.S. Food and Drug Administration (FDA);

- Presented key findings of translational research on Heat's proprietary algorithm verifying different tumor types share a variety of antigens which may be predictive of patient immune and clinical responses; and
- Announced encouraging preclinical systematic combination immunotherapy comparison data for anti-tumor vaccination with Heat's gp96-Ig platform alone and in combination with direct T cell costimulation.

"Throughout the first quarter, we remained focused on operational excellence and we made tremendous progress with the initiation of our HS-410 Phase 1/2 bladder cancer study and the FDA submission of our purposefully redesigned Phase 2 clinical protocol for HS-110 in NSCLC. Further, we strengthened our team with the appointment of a very knowledgeable Vice President of Research and Development, which is critical as we explore the depth, breadth and utility of our proprietary, 'off-the-shelf' [IMPACT](#) therapeutic vaccines. In addition, we formed a [Clinical Advisory Board](#) comprised of the world's leading cancer immunotherapy experts to work hand-in-hand with our team as we advance our clinical programs," said Jeff Wolf, Chief Executive Officer of Heat Biologics.

NEAR TERM MILESTONES

- Patient enrollment in Cohort 1 of Phase 1/2 HS-410 bladder cancer trial anticipated to be completed in the third quarter 2014;
- Patient enrollment and dosing in Phase 2 HS-110 lung cancer clinical study expected to begin in the third quarter 2014; and
- HS-410 bladder study Cohort 2 enrollment expected to be completed in the fourth quarter of 2014.

Mr. Wolf concluded, "I believe our focus on execution in the first quarter has set the stage for significant milestones in the coming months. The team has been working hard to prepare to commence the Phase 2 HS-110 lung cancer study, and we are on track to start patient enrollment in the third quarter of 2014. We believe these near-term key events will generate positive momentum as we approach 2015."

FIRST QUARTER 2014 FINANCIAL SNAPSHOT

As of March 31, 2014, cash, cash equivalents and short term investments totaled \$19.4 million. Based on Management's projections, the Company's current cash position is anticipated to continue to fund operations into the second half of 2015.

For the first quarter ended March 31, 2014, Heat Biologics reported a net loss of (\$2,422,966), and a net loss attributable to common stockholders of (\$2,330,597) or (\$0.36) per share as compared to a net loss of (\$788,461) and a net loss attributable to common stockholders of (\$3,063,856), or (\$1.66) per share for the first quarter ended March 31, 2013. The increase in the loss was primarily attributable to an increase of approximately \$93,339 in Research and Development expense, an increase of \$784,327 in Clinical and Regulatory expense and an increase of approximately \$746,734 in General and Administrative expense. The components of the increase in expenses are as follows:

The increase in Research and Development spending of \$93,339 is primarily related to an increase of \$147,376 in patent and licensing fees as part of the Company's continuing effort to maintain and expand its robust patent portfolio offset by a decrease of \$49,790 in pre-manufacturing costs associated with producing Heat Biologic's vaccines for use in clinical

trials plus changes in other various expenses.

The \$784,327 Clinical and Regulatory increase from the 2013 Quarter to the 2014 Quarter is attributable to increases in clinical trial execution costs of \$289,196, as well as increased manufacturing and drug handling costs of \$221,763 related to the production of vaccines for the Company's clinical trials. Additionally, costs associated with clinical trial strategy and regulatory functions increased by \$197,214. Personnel cost, including consultants and travel, increased by \$72,062. The remaining \$4,092 change is attributable to changes in various other expenses.

The increase of \$746,734 in General and Administrative expense was due to several items but primarily attributed to an increase of \$317,300 in professional services related to public company expenses and an increase of \$116,417 in directors and officers insurance related to being a public company. Personnel costs increased by \$269,902 including a non-cash incentive compensation (stock compensation expense) increase of \$162,482 and other costs related to expanding the Heat management team and hiring experienced personnel. Additional increases in administrative costs are associated with travel, office expenses, fees and other miscellaneous administrative costs associated with the Company's expansion.

About Heat Biologics, Inc.

Heat Biologics, Inc. 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 will be entering Phase 2 trials with its [HS-110](#) (Viagenpumatucl-L) against non-small cell lung cancer and is conducting Phase 1/2 clinical trials with its [HS-410](#) (Vesigenurtacel-L) against bladder cancer. For more information, please visit www.heatbio.com.

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, expected enrollment dates, shareholder value and achievement of near-term milestones. 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 Heat's ability to achieve its development and commercialization strategies, including its ability to obtain regulatory approvals. 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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