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Heat Biologics Reports First Quarter 2016 Financial Results

DURHAM, N.C., May 11, 2016 (GLOBE NEWSWIRE) -- [Heat Biologics, Inc.](#) ("Heat") (Nasdaq:HTBX), an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer, reported its financial results for the first quarter ended March 31, 2016.

"We are focused on achieving near-term milestones to rebuild shareholder value. Our primary goal is to advance HS-410 for the treatment of non-muscle invasive bladder cancer with one-year disease-free survival, immune response, safety and tolerability data expected in the fourth quarter of this year," said Jeff Wolf, Heat's Founder and CEO. "In addition, we are looking forward to presenting new data at the upcoming ASCO Annual Meeting in June around our Phase 1b trial evaluating HS-110 in combination with an anti-PD-1 checkpoint inhibitor for the treatment of non-small cell lung cancer."

Recent Developments & First Quarter 2016 Corporate Highlights

- In May, Heat had an abstract accepted for poster presentation at the ASCO Annual Meeting being held on June 3-7, 2016 in Chicago, IL. The poster is entitled "Broadening response rates to PD-1 therapy in advanced lung adenocarcinoma: Viagenpumatucel-L (HS-110) in combination with nivolumab in the ongoing DURGA trial" (Abstract #TPS9102). Abstracts will be made available on the ASCO website at www.asco.org in line with the conference's embargo policy.
- In April, Heat presented three posters at the AACR Annual Meeting. In the poster entitled "Phase I/II Study of Patients with Non-Muscle Invasive Bladder Cancer (NMIBC) Treated with Vesigenurtacel-L (HS-410) with or without BCG," Heat reported that no additional recurrences had been reported to-date, with all patients now at least 18 months out from enrollment. In another poster, Heat reported initial preclinical results from its collaboration with OncoSec Medical Incorporated in which researchers concluded that combining Heat's *ComPACT* vaccine with OncoSec's intratumoral DNA electroporation delivery platform stimulated an expansion of neoantigen-specific CD8+ T cells, leading to a regression in both treated and untreated cancer lesions in two mouse studies. In the third poster, Heat reported positive preclinical data on its next generation *ComPACT* platform technology, which combines a T cell priming vaccine and a T cell co-stimulator in a single product.
- In April, Heat implemented cost-saving measures and a focused corporate strategy to achieve data readout, with its current cash on-hand, anticipated in the fourth quarter of 2016 for its lead Phase 2 program evaluating HS-410 for the treatment of NMIBC. These cost-saving measures included a workforce reduction of approximately 22 percent of the company's headcount.

- In April, Heat appointed John Prendergast, Ph.D., to its Board of Directors.
- In March, Heat closed a public offering of approximately \$6.8 million in gross proceeds, which will primarily be used to complete its Phase 2 clinical trial evaluating HS-410 for the treatment of NMIBC. Remaining funds will be used to advance the current eight patients enrolled in our Phase 1b trial evaluating HS-110 in combination with nivolumab for the treatment of non-small cell lung cancer (NSCLC) through the reporting of topline data, as well as for licensing or acquisition of assets complementary to our existing programs and working capital and general corporate purposes.
- In March, Heat presented additional preclinical data from its *ComPACT* platform technology at the Keystone Symposia on Cancer Vaccines. Data presented demonstrated that *ComPACT* secreting OX40L generated the most potent immune response among other *ComPACT* co-stimulator variations including TL1A, 4-1BBL and ICOSL, as well as compared to systemic delivery of OX40 agonist antibody and vaccine alone.
- In February, Heat announced that it will no longer enroll new patients in its Phase 2 monotherapy trial arm evaluating HS-410 alone for the treatment of NMIBC following the resolution of the standard of care BCG shortage and discussions with the U.S. FDA. Heat anticipates reporting topline 6-month data from the 16 enrolled patients in the fourth quarter of 2016, contemporaneous with reporting data from Heat's BCG combination cohorts.
- In February, Heat announced that the U.S. FDA lifted the partial clinical hold on its HS-410 Phase 2 clinical trial and patient enrollment was resumed after less than one week; clinical timelines were materially unchanged. The partial clinical hold came after Heat concluded that the cell line on which HS-410 is based had been previously misidentified and immediately notified FDA of this conclusion. The FDA placed Heat's HS-410 Phase 2 clinical trial on partial clinical hold while they reviewed updated documentation. The partial clinical hold did not relate to concerns regarding the safety or efficacy of HS-410.
- In January, Heat reported three-month interim data from the unblinded, monotherapy arm in its Phase 2 trial evaluating HS-410 for the treatment of NMIBC. Images of the bladder taken from several patients treated with HS-410 alone showed changes that resemble T cell-rich structures that Heat has observed in biopsy samples, indicating that systemic administration with HS-410 leads to a localized immune response within the bladder that cannot be attributed to standard of care.

First Quarter 2016 Financial Highlights

- Research and development expenses decreased to approximately \$500,000 in the first quarter of 2016 compared to approximately \$504,000 in the first quarter of 2015, a decrease of approximately \$4,000. The decrease is attributable to reductions in patent, license and other professional fees offset by compensation costs associated with new

hires, as well as supplies and facilities as we bring more capabilities in-house.

- Clinical and regulatory expenses increased to approximately \$3.2 million in the first quarter of 2016 compared to approximately \$2.2 million in the first quarter of 2015, an increase of approximately \$1.0 million. The increase is attributable to clinical trial execution expenses, personnel costs and expenses related to the production of our clinical trial material.
- General and administrative expenses decreased to approximately \$1.0 million in the first quarter of 2016 compared to approximately \$1.3 million in the first quarter of 2015, a decrease of approximately \$0.3 million. The decrease is attributable to non-cash stock compensation expense for non-employees associated with the company's reduced share price, as well as reduced professional services and third party expenses.
- Net loss for the first quarter of 2016 was \$4.7 million compared to a net loss of \$4.0 million for the first quarter of 2015.
- Cash, cash equivalents and short-term investments totaled approximately \$11.8 million at March 31, 2016 compared to \$11.6 million at December 31, 2015. This includes the \$6.1 million in net proceeds raised during our March 2016 public offering.

About Heat Biologics, Inc.

Heat Biologics, Inc. (NASDAQ:HTBX) is an immuno-oncology company developing novel therapies that activate a patient's immune system against cancer. Heat's highly specific T cell-stimulating platform technologies, *ImPACT* and *ComPACT*, form the basis of its product candidates. These platforms, in combination with other therapies, such as checkpoint inhibitors, are designed to address three distinct but synergistic mechanisms of action: robust activation of CD8+ "killer" T cells (one of the human immune system's most potent weapons against cancer); reversal of tumor-induced immune suppression; and T cell co-stimulation to further enhance patients' immune response. Currently, Heat is conducting a Phase 2 trial with its HS-410 (vesigenurtacel-L) in patients with non-muscle invasive bladder cancer (NMIBC) and a Phase 1b trial with its HS-110 (viagenpumatucl-L) in combination with an anti-PD-1 checkpoint inhibitor to treat patients with non-small cell lung cancer (NSCLC). 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 new data to be presented at the upcoming ASCO Annual Meeting in June, the anticipated data readout in the fourth quarter of 2016 for Heat's lead Phase 2 program evaluating HS-410 for the treatment of NMIBC, anticipated reporting of topline 6-month data from the 16 enrolled patients in our Phase 2 monotherapy trial arm evaluating HS-410 in the fourth quarter of 2016 and the potential of Heat's *ImPACT* and *ComPACT* therapies. These statements are subject to a number of risks and uncertainties, many of which are difficult to

predict, including the ability of Heat's *ImPACT* and *ComPACT* therapies to perform as designed, the ability to enroll patients and complete the clinical trials on time, the other factors described in our annual report on Form 10-K for the year ended December 31, 2015 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.

Financial Statements

Heat Biologics, Inc. Condensed Consolidated Statements of Operations (Unaudited)

	Quarter ended March 31,	
	2016	2015
Operating expenses:		
Research and development	\$ 500,173	\$ 503,551
Clinical and regulatory	3,157,835	2,169,473
General and administrative	1,031,158	1,309,156
Loss from operations	(4,689,166)	(3,982,180)
Interest expense, net	(125,021)	(66,304)
Other income, net	79,701	21,617
Net loss	(4,734,486)	(4,026,867)
Net loss non-controlling interest	(174,883)	(117,669)
Net loss attributable to Heat Biologics, Inc.	<u>\$ (4,559,603)</u>	<u>\$ (3,909,198)</u>
Net loss per share attributable to Heat Biologics, Inc. -basic and diluted	<u>\$ (0.50)</u>	<u>\$ (0.57)</u>
Weighted-average number of common shares used in net loss per share calculation - basic and diluted	<u>9,124,641</u>	<u>6,814,863</u>

Condensed Consolidated Balance Sheets (Unaudited)

	March 31, 2016	December 31, 2015
Assets		
Cash, cash equivalents, and short term investments	\$ 11,835,487	\$ 11,629,598
Other assets	1,321,651	1,565,457
Total Assets	<u>\$ 13,157,138</u>	<u>\$ 13,195,055</u>
Liabilities and Stockholders' Equity		
Accounts payable and other liabilities	\$ 3,243,927	\$ 3,977,331
Long term debt, including current portion	5,942,175	6,722,994
Total Liabilities	9,186,102	10,700,325
Common stock	3,186	1,366
Additional paid-in-capital	54,851,230	48,566,451

Accumulated deficit	(48,990,306)	(44,430,703)
Accumulated other comprehensive loss	(162,391)	(86,584)
Non-Controlling Interest	(1,730,683)	(1,555,800)
Total Liabilities and Stockholders' Equity	\$ 13,157,138	\$ 13,195,055

CONTACT:

Heat Biologics, Inc.
 Jennifer Almond
 Investor and Media Relations
 919-240-7133
 investorrelations@heatbio.com



Source: Heat Biologics