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Atara Biotherapeutics Announces First Quarter 2017 Financial Results and Recent Highlights

SOUTH SAN FRANCISCO, Calif., May 04, 2017 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA) today reported financial results for the first quarter of 2017 and recent operational highlights.

"We continued to make important progress advancing our robust pipeline of T-cell therapies in the first quarter," said Isaac Ciechanover, Chief Executive Officer and President of Atara Biotherapeutics. "With the expected initiation of two Phase 3 trials this year and a conditional marketing authorization submission in the EU next year for our lead oncology product candidate, ATA129, we are on our way to becoming a commercial immunotherapy company. The recent data reported at AAN with autologous ATA188 in progressive multiple sclerosis also highlights the potential to expand our platform beyond oncology to include autoimmune disease."

Recent Highlights and Anticipated Upcoming Milestones

- Manufacture and testing of allogeneic Epstein-Barr virus (EBV)-Specific Cytotoxic T Lymphocytes (CTL), or ATA129, including assay refinement and discussions with FDA, are ongoing and continuing as planned.
 - Manufacturing lots to further support comparability evaluations and the Phase 3 trials.
- Plan to initiate two Phase 3 pivotal trials with ATA129 in EBV-Associated Post Transplant Lymphoproliferative Disorder (EBV-PTLD) in the second half of 2017.
 - Phase 3 trials intended to support approval in two indications: rituximab-refractory EBV-PTLD after hematopoietic cell transplant or solid organ transplant.
 - Planned Phase 3 sites include leading bone marrow and solid organ transplant centers in the US and Europe.
- Announced collaboration with Merck to evaluate KEYTRUDA® (pembrolizumab) in combination with ATA129 in nasopharyngeal carcinoma (NPC).
 - Phase 1/2 trial sponsored and conducted by Atara in patients with platinum resistant or recurrent NPC with pembrolizumab provided by Merck is planned to start in 2018.
- Obtained European Medicines Agency Scientific Advice for ATA129 under PRIME designation and plan to submit in 2018 a conditional marketing authorization (CMA) in Europe for the treatment of EBV-PTLD after hematopoietic cell transplant.
 - Plan to develop EU infrastructure to support CMA submission and potential

commercialization in Europe.

- Announced key management appointments as the Company expands operations and core capabilities, advances its pipeline and moves towards the potential commercialization of ATA129, including:
 - Joe Newell, Executive Vice President and Chief Technical Operations Officer, and
 - John Craighead, Vice President, Investor Relations and Corporate Communications.
- Atara's collaborating investigators announced positive interim results from an ongoing Phase 1 trial of autologous ATA188 in patients with progressive forms of multiple sclerosis (MS) at the American Academy of Neurology (AAN) Annual Meeting 2017.
 - Encouraging clinical improvements were observed in three of six progressive MS patients with advanced disease, which were correlated with CTL reactivity against target EBV antigens (EBV reactivity).
 - Ongoing autologous ATA188 Phase 1 trial estimated to complete enrollment in the third quarter of 2017.
- Expect to pursue clinical development of both autologous and allogeneic ATA188 to further inform and potentially accelerate the Company's development program in MS.
 - Based on FDA discussions, a planned Phase 1 allogeneic ATA188 trial in MS is on track to initiate in the second half of 2017.

First Quarter 2017 Financial Results

- Cash, cash equivalents and short-term investments as of March 31, 2017 totaled \$230.6 million, which the Company believes will be sufficient to fund planned operations into the first quarter of 2019.
- The Company reported net losses of \$25.7 million, or \$0.88 per share, for the first quarter of 2017, as compared to \$16.6 million, or \$0.58 per share, for the same period in 2016. Substantially all of the Company's net losses resulted from research and development expenses related to clinical and preclinical programs and from general and administrative expenses associated with operations.
- Research and development expenses were \$17.5 million for the first quarter of 2017, as compared to \$11.2 million for the same period in 2016. The increase in the first quarter of 2017 was due to costs associated with the Company's continuing expansion of research and development activities, including the following:
 - manufacturing and outside service costs related to the preparation for the two Phase 3 clinical trials of ATA129 in EBV-PTLD,
 - ongoing costs for the Company's expanded access protocol clinical trial for ATA129, which was initiated in mid-2016,
 - higher payroll and related costs from increased headcount, and
 - an increase in allocated facilities and information technology expenses.

Research and development expenses include \$2.1 million and \$2.2 million of non-cash stock-based compensation expenses in the first quarters of 2017 and 2016, respectively.

- General and administrative expenses were \$8.6 million for first quarter of 2017, as compared to \$5.8 million for the same period in 2016. The increase in the first quarter of 2017 was primarily due to an increase in payroll and related costs driven by increased headcount to support the Company's expanding operations and higher consulting, outside services and legal costs. General and administrative expenses include \$3.2 million and \$2.5 million of non-cash stock-based compensation expenses in the first quarters of 2017 and 2016, respectively.

About Atara's "Off-the-Shelf" Allogeneic Immunotherapy Platform

Atara's immunotherapy platform provides healthy immune capability to a patient and arms the immune system to precisely target and combat disease. T-cells derived from healthy donors are manufactured in advance and stored as inventory so that a customized unit of T-cells can be chosen for each patient. The T-cells are ready to infuse in approximately 3 to 5 days. Once administered, the T-cells home to their target, expand in-vivo to eliminate diseased cells, and eventually recede. This versatile platform can be directed towards a broad array of disease causing targets and has demonstrated clinical proof of concept across both viral and non-viral targets in conditions ranging from liquid and solid tumors to autoimmune and infectious diseases. The Company has pursued prospective feedback from health authorities on both manufacturing and clinical trial design. Atara's lead product candidate, ATA129, has the potential to be the first commercial allogeneic T-cell therapy for a viral target implicated in cancer.

About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. is a biopharmaceutical company developing meaningful therapies for patients with severe and life-threatening diseases who have been underserved by scientific innovation, with an initial focus on allogeneic T-cell therapies for cancer, autoimmune, and infectious disease. Atara's T-cell product candidates harness the power of the immune system to recognize and attack cancer cells and cells infected with certain viruses. The Company's initial clinical stage T-cell product candidates include Epstein-Barr virus targeted Cytotoxic T-cells (EBV-CTL), or ATA129, Cytomegalovirus targeted Cytotoxic T-cells (CMV-CTL), or ATA230, and Wilms Tumor 1 targeted Cytotoxic T-cells (WT1-CTL), or ATA520. These product candidates have demonstrated the potential to have therapeutic benefit in a number of clinical indications including hematologic malignancies, solid tumors, and refractory viral infections. The Company is also developing a next generation of T-cell product candidates utilizing a technology to selectively enhance a T-cell's ability to target specific viral proteins implicated in a disease. The Company's ATA188 product candidate leverages this technology. Initial clinical investigations employing this approach will focus on multiple sclerosis and other virally mediated cancers.

Forward-Looking Statements

This press release contains or may imply "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. For example, forward-looking statements include statements regarding: the Company's expected initiation of two Phase 3 clinical trials in the second half of 2017 with leading bone marrow and solid organ transplant centers in the U.S. and Europe and its plan to submit a conditional marketing authorization application in the EU for ATA129; the Company's continued growth and development as a commercial immunotherapy company

and its belief that it is advancing its product pipeline and moving towards the potential commercialization of ATA129; the Company's belief that it has been successful in producing ATA129 drug product; the Company's refinement of certain assays, manufacture of lots to further support comparability evaluations and the Phase 3 trials, and expectations to review these data with FDA prior to starting these trials; the Company's potential to expand its platform beyond oncology to include autoimmune disease; the Company's expected commencement of a Phase 1/2 trial with ATA129 and Merck's KEYTRUDA® in 2018; the Company's belief that its collaborating investigators' autologous ATA188 Phase 1 trial will be completed in 2017; the Company's expectation of pursuing clinical development of both autologous and allogeneic versions of ATA188 and the initiation of a Phase 1 allogeneic ATA188 trial in MS in the second half of 2017; and the Company's belief that its cash and investments as of March 31, 2017 will be sufficient to fund its planned operations into the first quarter of 2019. Because such statements deal with future events and are based on Atara Biotherapeutics' current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Biotherapeutics could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including those discussed under the heading "Risk Factors" in Atara Biotherapeutics' annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 9, 2017, including the documents incorporated by reference therein, and subsequent filings with the SEC. Except as otherwise required by law, Atara Biotherapeutics disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events or circumstances or otherwise.

ATARA BIOTHERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands)

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,430	\$ 47,968
Short-term investments	168,216	207,714
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	4,478	4,677
Total current assets	235,318	260,553
Property and equipment, net	4,400	3,259
Restricted cash - long-term	1,200	-
Other assets	820	102
Total assets	\$ 241,738	\$ 263,914
 Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,204	\$ 2,778
Accrued compensation	2,609	3,745
Accrued research and development expenses	2,106	2,408
Other accrued liabilities	886	744
Total current liabilities	7,805	9,675
Long-term liabilities	799	503
Total liabilities	8,604	10,178
 Commitments and contingencies		
 Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	436,096	431,075
Accumulated other comprehensive loss	(152)	(183)
Accumulated deficit	(202,813)	(177,159)
Total stockholders' equity	233,134	253,736
Total liabilities and stockholders' equity	\$ 241,738	\$ 263,914

ATARA BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended March	
	31,	
	2017	2016
Operating expenses:		
Research and development	\$ 17,541	\$ 11,247
General and administrative	8,620	5,814
Total operating expenses	<u>26,161</u>	<u>17,061</u>
Loss from operations	(26,161)	(17,061)
Interest and other income, net	509	503
Loss before provision for income taxes	(25,652)	(16,558)
Less: Provision for income taxes	2	3
Net loss	\$ (25,654)	\$ (16,561)
Other comprehensive loss:		
Unrealized gain on available-for-sale securities	31	569
Comprehensive loss	<u>\$ (25,623)</u>	<u>\$ (15,992)</u>
Net loss per common share:		
Basic and diluted net loss per common share	<u>\$ (0.88)</u>	<u>\$ (0.58)</u>
 Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	 <u>29,056</u>	 <u>28,542</u>

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Source: Atara Biotherapeutics, Inc.