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Atara Bio Announces Fourth Quarter and Full Year 2015 Financial Results and Recent Highlights

SOUTH SAN FRANCISCO, Calif., March 03, 2016 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a biopharmaceutical company focused on developing meaningful therapies for patients with severe and life-threatening diseases that have been underserved by scientific innovation, today reported financial results for the fourth quarter and full year 2015 and recent highlights.

"We are at an exciting juncture in the development of our allogeneic T-cell programs with the planned initiation of a multi-center early access clinical trial for EBV-CTL in the first half of 2016 and two Phase 3 pivotal trials later this year in EBV-PTLD. As a result, we believe that Atara has the potential to be the first to market allogeneic T cell therapies for viral targets," said Isaac Ciechanover, M.D., President and Chief Executive Officer of Atara Bio. "In addition, in the middle of this year, we expect to discuss with the FDA the plan for late phase development of our CMV-CTL product candidate to support registration in CMV infection."

Recent Highlights and Upcoming Milestones

- Granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the Company's Cytotoxic T Lymphocyte product candidate activated against Epstein-Barr virus (EBV-CTL) for the treatment of patients with EBV Post-Transplant Lymphoproliferative Disorder (EBV-PTLD) following hematopoietic cell transplant (HCT) or solid organ transplant (SOT).
 - Plan to initiate two Phase 3 pivotal trials of EBV-CTL for EBV-PTLD following HCT and SOT towards the end of 2016.
- Collaborating investigators at Memorial Sloan Kettering Cancer Center (MSK) presented additional positive results at the 2015 American Society of Hematology (ASH) Annual Meeting from an ongoing Phase 2 clinical trial and from patients treated under compassionate use with Atara's Cytomegalovirus-Targeted CTL (CMV-CTL) product candidate in patients with refractory CMV chorioretinitis and meningoencephalitis.
 - Overall response rate in 11 evaluable patients was approximately 73%, including seven complete responses and one partial response.
 - No graft versus host disease was observed.
- Collaborating investigators at MSK also presented positive clinical data at the 2015 ASH Annual Meeting from an ongoing Phase 1 clinical trial of Atara's primary donor-derived Wilms' Tumor 1 Targeted CTL (WT1-CTL) product candidate for patients with relapsed-refractory multiple myeloma, including plasma cell leukemia, following allogeneic HCT.

- Among seven patients treated, three achieved a complete remission (CR), one achieved a partial response, two had stable disease, and one had progressive disease by one year.
 - Two patients with plasma cell leukemia who developed a CR were in remission after one year.
 - There were no serious adverse events reported related to treatment with WT1-CTLs.
- Granted orphan drug designation by the FDA for the Company's molecularly targeted activin inhibitor, STM 434, for the treatment of ovarian cancer.
 - Initial data from the dose escalation portion of the STM 434 Phase 1 trial expected in the first half of 2016.
- Entered into exclusive license and research agreements with QIMR Berghofer Medical Research Institute.
 - Obtained an exclusive, worldwide license to develop and commercialize allogeneic, or "off-the-shelf", CTLs directed against multiple epitopes of EBV and CMV.
 - Complements ongoing CTL development efforts by selectively targeting certain epitopes and antigens.
 - Initial applications include the treatment of nasopharyngeal carcinoma, gastric cancer, and multiple sclerosis.

Fourth Quarter and Full Year 2015 Financial Results

- As of December 31, 2015, the Company had \$320.5 million in cash, cash equivalents and short-term investments. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our planned operations through 2018.
- The Company reported net losses of \$21.2 million and \$57.2 million for the fourth quarter and fiscal year 2015, as compared to \$10.5 million and \$28.0 million for the same periods in 2014. 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.
- Total research and development expenses increased to \$16.2 million and \$41.6 million for the fourth quarter and fiscal year 2015, as compared to \$5.0 million and \$15.4 million for the same periods in 2014. The increases in 2015 were primarily due to higher outside services costs and headcount-related expenses as a result of expanded clinical development activities, as well as from license fees of \$4.5 million and \$3.0 million in the second and fourth quarter, respectively.
- General and administrative expenses were \$5.5 million and \$16.8 million for the fourth quarter and fiscal year 2015, as compared to \$5.5 million and \$12.7 million for the same periods in 2014. The increase in fiscal year expense in 2015 was primarily due to increases in compensation-related expenses, legal fees and other outside services costs.

About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. is a biopharmaceutical company focused on developing meaningful therapies for patients with severe and life-threatening diseases that have been underserved by scientific innovation, with an initial focus on immunotherapy and oncology. Atara Bio's programs include T-cell product candidates and molecularly targeted product candidates. The T-cell product candidates include EBV-CTL, CMV-CTL and WT1-CTL and harness the power of the immune system to recognize and attack cancer cells and cells infected with certain viruses. The molecularly targeted product candidates include STM 434. These product candidates target activin and myostatin, members of the TGF-beta family of proteins, and have demonstrated the potential to have therapeutic benefit in a number of clinical indications.

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 potential for the allogeneic cellular therapy platform to provide efficacy, safety, and manufacturing benefits over other approaches; the potential for such platform to be applicable to a wide array of indications; the initiation of the planned multi-center early access clinical trial in the first half of this year and pivotal trials with EBV-CTL for EBV-PTLD following HCT and SOT towards the end of 2016; the potential approval of EBV-CTL in PTLD after HCT or SOT as well as any marketing exclusivity derived from the orphan designation; the timing of the initial data from the STM 434 Phase 1 dose escalation trial in the first half of 2016; the potential approval of STM 434 in ovarian cancer as well as any marketing exclusivity derived from the orphan designation; the potential to be the first to the market with allogeneic T cell therapies for viral targets; and the belief that our existing cash, cash equivalents and short-term investments will be sufficient to fund our planned operations through 2018. Because such statements deal with future events and are based on Atara Bio's current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Atara Bio 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 Bio's quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 6, 2015, including the documents incorporated by reference therein, and subsequent filings with the SEC. Except as otherwise required by law, Atara Bio 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.
Consolidated Balance Sheets
(Unaudited)
(In thousands)

	As of December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,746	\$ 21,897
Short-term investments	296,736	82,219
Restricted cash	194	—
Prepaid expenses and other current assets	3,921	1,910
Total current assets	324,597	106,026
Property and equipment, net	270	48
Other assets	108	48
Total assets	<u>\$ 324,975</u>	<u>\$ 106,122</u>

Liabilities and stockholders' equity

Current liabilities:		
Accounts payable	\$ 1,445	\$ 440
Accrued compensation	2,624	1,225
Accrued research and development expenses	5,112	824
Other accrued liabilities	528	235
Total current liabilities	9,709	2,724
Long-term liabilities	166	216
Total liabilities	9,875	2,940

Commitments and contingencies

Stockholders' equity:		
Common stock	3	2
Additional paid-in capital	413,725	144,169
Accumulated other comprehensive loss	(518)	(100)
Accumulated deficit	(98,110)	(40,889)
Total stockholders' equity	315,100	103,182
Total liabilities and stockholders' equity	<u>\$ 324,975</u>	<u>\$ 106,122</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 16,231	\$ 5,048	\$ 41,618	\$ 14,380
Research and development costs paid to Amgen	—	—	—	1,066
General and administrative	5,539	5,548	16,830	12,710
Total operating expenses	<u>21,770</u>	<u>10,596</u>	<u>58,448</u>	<u>28,156</u>
Loss from operations	(21,770)	(10,596)	(58,448)	(28,156)
Interest and other income, net	522	66	1,218	125
Loss before provision for income taxes	(21,248)	(10,530)	(57,230)	(28,031)
Provision (benefit) for income taxes	-	(3)	(9)	(25)
Net loss	\$ (21,248)	\$ (10,527)	\$ (57,221)	\$ (28,006)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(569)	(89)	(418)	(100)
Comprehensive loss	<u>\$ (21,817)</u>	<u>\$ (10,616)</u>	<u>\$ (57,639)</u>	<u>\$ (28,106)</u>
Net loss per common share:				
Basic and diluted net loss per common share	<u>\$ (0.75)</u>	<u>\$ (0.67)</u>	<u>\$ (2.24)</u>	<u>\$ (5.62)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	<u>28,413</u>	<u>15,805</u>	<u>25,583</u>	<u>4,986</u>

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