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Atara Biotherapeutics Announces Second Quarter 2017 Financial Results and Recent Highlights

SOUTH SAN FRANCISCO, Calif., Aug. 07, 2017 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a leading "off-the-shelf" T-cell immunotherapy company developing novel treatments for patients with cancer and multiple sclerosis (MS), today reported financial results for the second quarter of 2017 and recent operational highlights.

"In the second quarter, we made significant progress toward the initiation of two Phase 3 clinical studies for ATA129, anticipated to begin in the second half of 2017," said Isaac Ciechanover, Chief Executive Officer and President of Atara Biotherapeutics. "We also continue to build Atara's commercial capabilities, highlighted by the recent appointment of Dr. Derrell Porter as Global Commercial Head and the establishment of our EU headquarters in Zug, Switzerland. Looking forward, as we advance our innovative pipeline of T-cell immunotherapies for cancer and multiple sclerosis, we anticipate the opportunity to present new data at major medical conferences this year and throughout 2018."

Recent Highlights and Anticipated Upcoming Milestones

- Manufacture of ATA129, an allogeneic Epstein-Barr virus (EBV)-specific T-cell immunotherapy, to support Phase 3 clinical studies is ongoing and continuing as planned.
 - Currently generating comparability data using Atara's refined assays and contract manufacturing organization (CMO)-produced cell lines.
- Expect to initiate two Phase 3 clinical studies with ATA129 in EBV-associated post-transplant lymphoproliferative disorder (EBV-PTLD) in the second half of 2017 following completion of comparability testing and submission of the data to the U.S. Food and Drug Administration (FDA).
 - Additional details on the Phase 3 clinical study designs in rituximab-refractory EBV-PTLD after hematopoietic cell transplant (HCT) or solid organ transplant (SOT) will be provided at initiation.
- Continue to build core commercial capabilities in preparation for the expected submission of the ATA129 conditional marketing authorization in the EU in 2018 and subsequent launch.
 - Appointed Dr. Derrell Porter as Senior Vice President, Global Commercial Head who brings extensive oncology and specialty commercialization experience to the management team.
 - Established Atara's EU headquarters in Zug, Switzerland and began recruiting key global functional leadership and staff.

- ATA129 expanded access protocol (EAP) clinical study for patients with EBV-PTLD and other EBV-positive hematologic and solid tumors is ongoing at more than 10 medical centers.
 - Multicenter data from the EAP clinical study is expected to be presented at appropriate future scientific conferences.
- Atara's collaborating investigators completed enrollment of the ongoing Phase 1 study of autologous ATA188 in patients with progressive MS.
- New MS data to be presented by Atara's collaborating investigators at the upcoming MSParis2017 Congress, the 7th Joint Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) meeting, October 25-28, 2017 in Paris, France.
 - Updated, interim results from the Phase 1 study of autologous ATA188 in patients with progressive MS.
 - New results characterizing the molecular signature of EBV in MS brain lesions.
- Upcoming additional development milestones for Atara's innovative pipeline of T-cell immunotherapies include:
 - Expanded clinical development of autologous and allogeneic ATA188 in MS, including a planned Phase 1 allogeneic ATA188 clinical study expected to initiate in the second half of 2017.
 - A Phase 1/2 clinical study of ATA129 in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA® (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated nasopharyngeal carcinoma (NPC) planned to start in 2018.

Second Quarter 2017 Financial Results

- Cash, cash equivalents and short-term investments as of June 30, 2017 totaled \$216.9 million, which the Company believes will be sufficient to fund planned operations into the first quarter of 2019. In the period from May 24, 2017 to July 26, 2017, the Company sold approximately 1.3 million shares of Common Stock pursuant to the Company's "at-the-market" (ATM) facility, for gross proceeds before deducting underwriting discounts and commissions and other estimated offering expenses of \$20.0 million, with \$9.8 million occurring through June 30, 2017.
- The Company reported net losses of \$27.4 million, or \$0.94 per share, for the second quarter of 2017, as compared to \$18.9 million, or \$0.66 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 \$18.3 million for the second quarter of 2017, as compared to \$13.0 million for the same period in 2016. The increase in the second 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 studies of ATA129 in EBV-PTLD;
 - Ongoing costs for the Company's EAP clinical study 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 \$2.0 million and \$2.4 million of non-cash stock-based compensation expenses in the second quarters of 2017 and 2016, respectively.
 - General and administrative expenses were \$9.6 million for second quarter of 2017, as compared to \$6.5 million for the same period in 2016. The increase in the second quarter of 2017 was primarily due to an increase in compensation-related costs driven by increased headcount to support the Company's expanding operations and higher consulting and outside services costs. General and administrative expenses include \$3.7 million and \$2.7 million of non-cash stock-based compensation expenses in the second quarters of 2017 and 2016, respectively.

About EBV-PTLD

Since its discovery as the first human oncovirus, Epstein-Barr virus (EBV) has been implicated in the development of a wide range of lymphoproliferative disorders, including lymphomas and other cancers. EBV is widespread in all human populations and persists as a lifelong, asymptomatic infection. In immunocompromised patients, such as those undergoing hematopoietic cell transplants (HCT) or solid organ transplants (SOT), EBV-associated post-transplant lymphoproliferative disorder (EBV-PTLD), represents a life-threatening condition. Median overall survival in EBV-PTLD patients after HCT who have failed rituximab-based first line therapy is 16-56 days. In EBV-PTLD following SOT, patients failing rituximab experience increased chemotherapy-induced treatment-related mortality compared to other lymphoma patients. One and two-year survival in high-risk EBV-PTLD patents after SOT is 36% and 0%, respectively.

About ATA129

Atara's most advanced T-cell immunotherapy in development, ATA129, is a potential treatment for cancer patients with rituximab refractory EBV-PTLD as well as other EBV positive hematologic and solid tumors including nasopharyngeal carcinoma (NPC). In February 2015, FDA granted ATA129 Breakthrough Therapy Designation for EBV-PTLD following allogeneic hematopoietic cell transplant (HCT) and in October 2016, ATA129 was accepted into the EMA Priority Medicines (PRIME) regulatory pathway for the same indication, providing enhanced regulatory support. In addition, ATA129 also has orphan status in the U.S. and EU. Phase 3 studies of ATA129 in EBV-PTLD after HCT or solid organ transplant (SOT) are expected to start in 2017, and a Phase 1/2 study in NPC is planned for 2018. ATA129 is also available to eligible patients with EBV-positive tumors through an ongoing multicenter expanded access protocol (EAP) clinical study. Atara expects to submit ATA129 for conditional marketing authorization in EBV-PTLD following HCT in the EU in 2018.

About Progressive Multiple Sclerosis

Progressive Multiple Sclerosis (PMS) is a severe disease with few therapeutic options. PMS

comprises two conditions, both characterized by persistent progression and worsening of MS symptoms and physical disability over time. This is distinct from Relapsing Remitting MS (RRMS) where flares of the disease are followed by periods of recovery and quiescence. Primary Progressive MS (PPMS) occurs when continuous progressive disease is present at diagnosis. Secondary Progressive MS (SPMS) initially begins as RRMS and develops into a progressive form. There is substantial unmet medical need for new and effective therapies for patients with PPMS and SPMS. Most treatment options that work well in reducing flares in RRMS have not been shown to be effective in slowing or reversing disability in PMS.

About ATA188

Epstein-Barr Virus (EBV) is associated with a wide range of hematologic malignancies and solid tumors, as well as certain autoimmune conditions such as multiple sclerosis (MS). ATA188, the Company's next generation T-cell immunotherapy for autoimmune diseases, has the potential to selectively target and eliminate EBV-infected B-cells and plasma cells in the central nervous system that may catalyze autoimmune responses and MS pathophysiology. As reported at the American Academy of Neurology (AAN) meeting in April 2017, the first study to test adoptive immunotherapy in patients with MS showed that autologous ATA188 led to encouraging clinical improvements in MS symptoms that correlated with the EBV reactivity of ATA188 in 3 of 6 patients. No patient in the study experienced progression of disability or worsening in Expanded Disability Status Scale (EDSS). Additional reported results are available [at this link](#). In addition to the ongoing Phase 1 clinical study of autologous ATA188 in progressive forms of MS, a Phase 1 allogeneic ATA188 clinical study is expected to begin in the second half of 2017.

About Atara Biotherapeutics, Inc.

[Atara Biotherapeutics, Inc. \(@Atarabio\)](#) is a leading cell therapy company developing novel treatments for patients with cancer and multiple sclerosis (MS). The Company's "off-the-shelf", or allogeneic, T-cells are engineered from donors with healthy immune function and allow for rapid delivery from inventory to patients without a requirement for pretreatment. Atara's T-cell immunotherapies are designed to precisely recognize and eliminate cancerous or diseased cells without affecting normal, healthy cells. Atara's most advanced T-cell immunotherapy in development, ATA129, is being developed for the treatment of cancer patients with rituximab refractory Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV-PTLD), as well as other EBV positive hematologic and solid tumors including nasopharyngeal carcinoma (NPC). ATA188, the Company's next generation T-cell immunotherapy for autoimmune diseases, selectively targets specific EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). A Phase 1 clinical study of autologous ATA188 in progressive forms of MS is ongoing, and a Phase 1 allogeneic ATA188 clinical study is expected to begin in the second half of 2017. Atara's clinical pipeline also includes ATA520 targeting Wilms Tumor 1 (WT1) and ATA230 directed against cytomegalovirus (CMV).

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 following completion of comparability testing and submission of the comparability data to FDA; the Company's belief that it has been successful in producing ATA129 drug product to

support its Phase 3 clinical studies and that it is generating comparability data using the Company's refined assays and its CMO's produced cell lines; the Company's expectation of providing additional details on the Phase 3 clinical study designs at the time of initiation of the trials; the Company's expected submission of a conditional marketing authorization application in the EU in 2018 for ATA129; the Company's belief that it is moving towards the potential commercialization of ATA129 and the build out of commercial capabilities; the Company's expected commencement of a Phase 1/2 trial with ATA129 and Merck's KEYTRUDA® in 2018; the Company's belief that it will expand clinical development of autologous and allogeneic ATA188 in MS, including a planned Phase I allogeneic ATA188 clinical study expected to initiate in the second half of 2017; the Company's belief that it and its collaborating partners will have the opportunity to present new data at major medical conferences this year and throughout 2018, including data from the Company's multicenter EAP clinical study; and the Company's belief that its cash and investments as of June 30, 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' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 4, 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)

	<u>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets		
Current assets:		
Cash and cash equivalents	\$64,237	\$47,968
Short-term investments	152,659	207,714
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	5,402	4,677
Total current assets	<u>222,492</u>	<u>260,553</u>
Property and equipment, net	20,287	3,259
Restricted cash - long-term	1,200	—
Other assets	176	102
Total assets	<u>\$244,155</u>	<u>\$263,914</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$5,243	\$2,778
Accrued compensation	3,262	3,745
Accrued research and development expenses	2,071	2,408
Other accrued liabilities	905	744

Total current liabilities	11,481	9,675
Long-term liabilities	11,530	503
Total liabilities	23,011	10,178
Commitments and contingencies		
Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	451,496	431,075
Accumulated other comprehensive loss	(114)	(183)
Accumulated deficit	(230,241)	(177,159)
Total stockholders' equity	221,144	253,736
Total liabilities and stockholders' equity	\$244,155	\$263,914

Atara Biotherapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended June		Six Months Ended June 30,	
	30,			
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$18,296	\$12,991	\$35,837	\$24,238
General and administrative	9,613	6,494	18,233	12,308
Total operating expenses	27,909	19,485	54,070	36,546
Loss from operations	(27,909)	(19,485)	(54,070)	(36,546)
Interest and other income, net	481	605	990	1,108
Loss before provision for income taxes	(27,428)	(18,880)	(53,080)	(35,438)
Less: Provision for income taxes	—	—	2	3
Net loss	\$(27,428)	\$(18,880)	\$(53,082)	\$(35,441)
Other comprehensive loss:				
Unrealized gain on available-for-sale securities	38	142	69	711
Comprehensive loss	\$(27,390)	\$(18,738)	\$(53,013)	\$(34,730)
Net loss per common share:				
Basic and diluted net loss per common share	\$(0.94)	\$(0.66)	\$(1.82)	\$(1.24)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	29,247	28,665	29,152	28,603

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