

Atara Biotherapeutics Announces Third Quarter 2017 Financial Results and Recent Highlights

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2017 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq:ATRA), a leading off-the-shelf T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune diseases and serious viral infections, today reported financial results for the third quarter of 2017 and recent operational highlights.

“We made great progress in the third quarter advancing our off-the-shelf T-cell immunotherapy pipeline,” said Isaac Ciechanover M.D., Chief Executive Officer and President of Atara Biotherapeutics. “We are at the cusp of initiating our Phase 3 clinical studies for ATA129 in EBV-associated lymphoma, which we expect to do by the end of this year pending FDA alignment on product comparability. We also made substantial progress moving our multiple sclerosis programs forward through the recent initiation of a Phase 1 study for allogeneic ATA188 and presentation of positive autologous ATA190 results at MS Paris 2017.”

Recent Highlights and Anticipated Upcoming Milestones

- Completed manufacture of ATA129, an off-the-shelf Epstein-Barr virus (EBV)-specific T-cell immunotherapy, to support Phase 3 comparability assessment.
 - Generated data that we believe support comparability, and we are in discussions with the U.S. Food and Drug Administration (FDA) regarding comparability and Phase 3 study initiation.
- Expect to initiate two Phase 3 clinical studies with ATA129 in EBV-associated post-transplant lymphoproliferative disorder (EBV-PTLD) by the end of 2017.
- Received positive regulatory feedback from Health Canada supporting an expedited approval pathway for ATA129 in rituximab-refractory EBV-PTLD following hematopoietic cell transplant (HCT).
- Announced positive interim results from a multicenter expanded access study of ATA129 for patients with EBV-associated cancers will be presented at the 59th American Society of Hematology (ASH) Annual Meeting in December. Highlights from the published abstract include:
 - Safety and efficacy results in ten patients from the planned Phase 3 populations with rituximab-refractory EBV-associated post-transplant lymphoproliferative disorder (EBV-PTLD), five with EBV-PTLD following solid organ transplant (SOT) and five with EBV-PTLD following HCT were presented.

- At the time of abstract submission in August 2017, all five patients with EBV-PTLD after SOT and four of the five patients with EBV-PTLD after HCT responded to treatment.
 - An additional two EBV-PTLD patients received ATA129 and were too early in the follow-up period to assess.
 - An additional ten patients with other EBV-associated cancers received ATA129 and were included in the safety population.
 - ATA129 was generally well-tolerated. Treatment-related, treatment-emergent serious adverse events (SAEs) were reported in five of the 22 treated patients (two in EBV-PTLD and three in other EBV associated cancers patients). A tumor flare was observed in one patient.
 - Updated safety and efficacy results will be presented at the meeting.
- Initiated a multinational, multicenter Phase 1 clinical study to evaluate allogeneic ATA188 in patients with progressive or relapsing-remitting multiple sclerosis (MS).
 - The open-label, single-arm study is expected to enroll a total of 60 patients: 30 patients with progressive forms of MS, either primary progressive MS (PPMS) or secondary progressive MS (SPMS), and 30 patients with relapsing-remitting MS (RRMS).
 - The primary objective of the Phase 1 clinical study is to assess the safety of allogeneic ATA188 in subjects observed for at least 1 year after the first dose. Key secondary endpoints in the study include measures of clinical efficacy such as expanded disability status scale (EDSS) scores and annualized relapse rate (ARR) as well as MRI imaging.
- Reported updated positive results from an ongoing Phase 1 study of autologous ATA190 in patients with primary or secondary progressive MS at MSParis2017 Congress, the 7th Joint Meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS).
 - Six of ten progressive MS patients experienced clinical improvements, including three who improved their EDSS score. Clinical improvements were observed from an established level of disability. Reduction in fatigue was a consistent observation in responding patients.
 - Autologous ATA190 was well-tolerated, and no significant treatment-related adverse events were observed in the study.
 - A correlation between clinical improvement and the reactivity of autologous ATA190 against target EBV antigens (EBV reactivity) was also observed.
- Expanded leadership team with the appointment of Dr. Kanya Rajangam as Senior Vice President and Chief Medical Officer.
 - Dr. Rajangam has extensive global oncology clinical development experience, including advancing multiple early- and late-stage programs.
- Updated positive ATA230 results in patients with cytomegalovirus (CMV) viremia and

disease post-transplant will also be presented at ASH.

- The reported response rate of 64% in all patients was similar in those with CMV viremia and disease. One of the 32 patients who responded died of CMV disease.
 - Five patients experienced grade 3 or higher adverse events deemed possibility related to ATA230.
- Granted rare pediatric disease designation for ATA230 in congenital CMV infection, as well as orphan drug designation in CMV viremia and disease by the FDA.

Third Quarter 2017 Financial Results

- Cash, cash equivalents and short-term investments as of September 30, 2017 totaled \$200.2 million, which the Company believes will be sufficient to fund planned operations into the first quarter of 2019.
- The Company reported net losses of \$31.1 million, or \$1.02 per share, for the third quarter of 2017, as compared to \$25.4 million, or \$0.88 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 \$20.6 million for the third quarter of 2017, as compared to \$18.8 million for the same period in 2016. The increase in the third 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 expanded access protocol 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 \$2.1 million and \$2.6 million of non-cash stock-based compensation expenses in the third quarters of 2017 and 2016, respectively.
- General and administrative expenses were \$11.1 million for third quarter of 2017, as compared to \$7.1 million for the same period in 2016. The increase in the third 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 and outside services. General and administrative expenses include \$3.9 million and \$2.7 million of non-cash stock-based compensation expenses in the third 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 patients 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. Atara also received positive regulatory feedback from Health Canada in September 2017 supporting the submission of ATA129 for an expedited approval pathway. In addition, ATA129 also has orphan status in the U.S. and EU. Phase 3 studies of ATA129 in EBV-PTLD after HCT (MATCH study) or solid organ transplant (ALLELE study) 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 Multiple Sclerosis

MS is a chronic neurological autoimmune disease that affects an estimated 2.3 million people around the world. Relapsing-remitting MS (RRMS) is the most common form of MS and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. Despite available disease-modifying treatments, most individuals with RRMS continue to experience disease activity and disability progression.

Progressive MS (PMS) is a severe form of the disease with few therapeutic options. PMS comprises two conditions, both characterized by persistent progression and worsening of MS symptoms and physical disability over time. Primary Progressive MS (PPMS) occurs when continuous progressive disease is present at diagnosis and occurs in approximately 15% of newly diagnosed cases. Secondary Progressive MS (SPMS) initially begins as RRMS and develops into a progressive form. Up to 80% of people with RRMS will eventually develop SPMS. 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 allogeneic ATA188 and autologous ATA190

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). T-cells are a critical component of the body's immune system and can selectively target specific EBV antigens believed to be important for the potential treatment of MS. Allogeneic ATA188 and autologous ATA190, the Company's next generation T-cell immunotherapies developed by Professor Rajiv Khanna at QIMR Berghofer, have the potential to precisely recognize and eliminate EBV-infected B-cells and plasma cells in the central nervous system that may catalyze autoimmune responses and MS pathophysiology. Professor Michael Pender from The University of Queensland presented initial interim results from the first autologous ATA190 study, which was partially funded by MS Research Australia, MS Queensland and Perpetual Foundation, at the American Academy of Neurology (AAN) meeting in April 2017. This study tested adoptive immunotherapy in patients with MS and showed that autologous ATA190, led to encouraging clinical improvements in MS symptoms that correlated with autologous ATA190's reactivity against target EBV antigens (EBV reactivity). In addition to the ongoing Phase 1 autologous ATA190 clinical study in patients with progressive MS, Atara also initiated a multinational, multicenter Phase 1 allogeneic ATA188 clinical study in patients with progressive or relapsing-remitting MS in October 2017.

About CMV

In patients with weakened immune systems, including bone marrow and solid organ transplant recipients, newborns with immature immune systems and those with human immunodeficiency virus (HIV), cytomegalovirus (CMV) can cause potentially life-threatening disease or may result in blindness, brain damage and deafness. While small-molecule antiviral drugs are approved to treat and prevent CMV infection, there remains a high unmet need due to viral resistance, modest neurodevelopmental activity and adverse effects, such as toxicity and reduction in white blood cell count impairing the ability to fight other infections, with these agents.

About ATA230

ATA230, an allogeneic T-cell immunotherapy targeting antigens expressed by CMV, has been investigated in one Phase 1 and two Phase 2 clinical studies in immunocompromised patients with CMV viremia or disease who are refractory or resistant to antiviral drug treatment in the post-transplant setting. In October 2017, Atara announced that ATA230 was granted Rare Pediatric Disease Designation for the treatment of congenital cytomegalovirus (CMV) infection by FDA and in September 2017, ATA230 received orphan drug designation in the U.S. for the treatment of CMV viremia and disease in immunocompromised patients. The European Medicines Agency (EMA) in October 2016 also issued a positive orphan drug designation opinion for ATA230 for the treatment of CMV infection in patients with impaired cell-mediated immunity. Atara intends to further evaluate ATA230 development plans with the FDA and other global health authorities following the initiation of ATA129 EBV-PTLD Phase 3 studies.

About Atara Biotherapeutics, Inc.

[Atara Biotherapeutics, Inc. \(@Atarabio\)](#) is a leading T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune diseases and serious viral infections. 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). Phase 3 studies of ATA129 in EBV-PTLD following a hematopoietic cell transplant (MATCH study) or solid organ transplant (ALLELE study) are expected to start in 2017, and a Phase 1/2 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 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 hematopoietic cell transplant in the EU in 2018. Allogeneic ATA188 and autologous ATA190, the Company's next generation T-cell immunotherapies, selectively target specific EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). A Phase 1 clinical study of autologous ATA190 in patients with progressive MS is ongoing. Atara also initiated a multinational, multicenter Phase 1 allogeneic ATA188 clinical study in patients with progressive or relapsing-remitting MS in October 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 Phase 1 clinical study to evaluate allogeneic ATA188 is expected to enroll a total of 60 patients, 30 patients with progressive forms of MS and 30 patients with RRMS; ATA188 and ATA190 have the potential to precisely recognize and eliminate EBV-infected B-cells and plasma cells in the central nervous system that may catalyze autoimmune responses and MS pathophysiology; the Company's expected initiation of Phase 3 studies of ATA129 in EBV-PTLD following a hematopoietic cell transplant or solid organ transplant in 2017 and a Phase 1/2 study of ATA129 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated NPC in 2018; the Company's expected submission of a conditional marketing authorization application in EBV-PTLD following HCT in the EU in 2018; the Company's intention to further evaluate ATA230 development plans with the FDA and other global health authorities following the initiation of ATA129 EBV-PTLD Phase 3 studies; and the Company's belief that its cash and investments as of September 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 August 7, 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>September 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 60,493	\$ 47,968
Short-term investments	139,728	207,714
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	5,802	4,677
Total current assets	<u>206,217</u>	<u>260,553</u>
Property and equipment, net	22,176	3,259
Restricted cash - long-term	1,200	—
Other assets	100	102
Total assets	<u>\$ 229,693</u>	<u>\$ 263,914</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,539	\$ 2,778
Accrued compensation	5,319	3,745
Accrued research and development expenses	3,810	2,408
Other accrued liabilities	1,848	744
Total current liabilities	<u>16,516</u>	<u>9,675</u>
Long-term liabilities	7,221	503
Total liabilities	<u>23,737</u>	<u>10,178</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock	3	3
Additional paid-in capital	467,378	431,075
Accumulated other comprehensive loss	(88)	(183)
	(261,337)	(177,159)
Accumulated deficit		
Total stockholders' equity	<u>205,956</u>	<u>253,736</u>
Total liabilities and stockholders' equity	<u>\$ 229,693</u>	<u>\$ 263,914</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 20,598	\$ 18,802	\$ 56,435	\$ 43,040
General and administrative	11,062	7,140	29,295	19,448
Total operating expenses	31,660	25,942	85,730	62,488
Loss from operations	(31,660)	(25,942)	(85,730)	(62,488)
Interest and other income, net	564	576	1,554	1,684
Loss before provision for income taxes	(31,096)	(25,366)	(84,176)	(60,804)
Provision for income taxes	—	7	2	10
Net loss	\$ (31,096)	\$ (25,373)	\$ (84,178)	\$ (60,814)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	26	(158)	95	553
Comprehensive loss	<u>\$ (31,070)</u>	<u>\$ (25,531)</u>	<u>\$ (84,083)</u>	<u>\$ (60,261)</u>
Net loss per common share:				
Basic and diluted net loss per common share	<u>\$ (1.02)</u>	<u>\$ (0.88)</u>	<u>\$ (2.84)</u>	<u>\$ (2.12)</u>
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	<u>30,474</u>	<u>28,801</u>	<u>29,597</u>	<u>28,670</u>

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