

Atara Biotherapeutics Announces Third Quarter 2019 Financial Results and Recent Clinical, Operational and Strategic Progress

SOUTH SAN FRANCISCO, Calif., Nov. 07, 2019 (GLOBE NEWSWIRE) -- Atara Biotherapeutics, Inc. (Nasdaq: ATRA), a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases, today reported financial results for the third quarter of 2019 and recent business highlights.

"I am pleased with our recent clinical, operational and strategic progress," said Pascal Touchon, President and Chief Executive Officer of Atara Biotherapeutics. "Following a comprehensive strategic portfolio review, we will focus our resources going forward on innovative off-the-shelf, allogeneic T-cell immunotherapy programs, specifically tab-cel[®], ATA188, ATA2271/ATA3271 and ATA3219. In parallel, we will continue to leverage the capabilities and expertise of external partners for development of autologous CAR T immunotherapies."

Following a six-month assessment of patients with progressive multiple sclerosis (MS) enrolled in cohort 3 of an ATA188 Phase 1a study, Atara selected this cohort 3 dose to initiate the randomized, double-blind, placebo-controlled Phase 1b part of this study.

"We are encouraged by the safety profile and early findings of potential efficacy for people living with progressive MS, as shown in our Phase 1a study data presented at ECTRIMS in September," said AJ Joshi, MD, Senior Vice President and Chief Medical Officer of Atara Biotherapeutics. "The decision to initiate the Phase 1b was based on achieving in cohort 3 our pre-determined criteria of a continued well-tolerated safety profile and at least 50 percent of patients achieving clinical improvement from more than one clinical study site using the criteria we defined at ECTRIMS. Recognizing these are early data, and incorporating input from external experts, we believe these results merit the acceleration of ATA188 development for progressive MS patients who have limited treatment options and in whom continual clinical decline is expected."

Recent Highlights and Anticipated Upcoming Milestones

61st American Society of Hematology (ASH) Annual Meeting

- Announced four abstracts highlighting robust off-the-shelf, allogeneic T-cell immunotherapy pipeline and next-generation CAR T technologies to be presented at the 61st ASH Annual Meeting, December 7-10, 2019 in Orlando, Florida
- Among these data are tab-cel[®] long-term clinical outcomes from a multicenter

expanded access protocol (EAP) study for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD)

-- 26 relapsed/refractory EBV+ PTLD patients were treated in a multicenter tab-cel[®] EAP study including a subgroup of 22 patients who would have likely met eligibility criteria for Atara's ongoing tab-cel[®] Phase 3 studies

-- An overall response rate (ORR) of 55 and 82 percent was observed in this subgroup of patients with EBV+ PTLD following allogeneic hematopoietic cell transplant (HCT) and solid organ transplant (SOT), respectively

-- Estimated 2-year overall survival (OS) in this subgroup was 79 and 81 percent for HCT and SOT, respectively

- Atara will present additional findings describing the hospitalization burden of patients with EBV+ PTLD
- Atara's Moffitt Cancer Center collaborators to present two abstracts detailing next-generation CAR T technologies

Tab-cel[®] (tabelecleucel)

- Atara continues to progress tab-cel[®] Phase 3 development for patients with EBV+ PTLD

-- Atara remains on track to initiate a tab-cel[®] biologics license application (BLA) submission for patients with EBV+ PTLD in the second half of 2020

-- In the U.S. and Australia, 35 sites are available for enrollment and the company is preparing to open additional sites in the U.S. and Canada

-- Atara plans to submit a clinical trial application (CTA) to several European countries by the end of 2019 to enable opening EU clinical sites next year

- Atara continues to see strong tab-cel[®] investigator, physician and patient interest, and in cases where the company is not able to enroll patients in its EBV+ PTLD Phase 3 clinical studies, Atara is providing tab-cel[®] to patients in need under its early access and single patient use programs
- Atara is in discussions with the European Medicines Agency (EMA) and the outcome of these discussions will determine the timing of the tab-cel[®] EU conditional marketing authorization (CMA) application for patients with EBV+ PTLD
- Studies supporting potential additional tab-cel[®] indications are also advancing
 - A Phase 1/2 clinical study of tab-cel[®] 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) is currently enrolling
 - Atara expects to initiate enrollment in a Phase 2 multi-cohort study including patients with other EBV+ cancers in the second half of 2020

ATA188 for Multiple Sclerosis (MS)

- Following a six-month assessment of patients with progressive MS enrolled in cohort 3 of an ATA188 Phase 1a study, Atara selected this dose to initiate the randomized, double-blind, placebo-controlled Phase 1b part of this study
- In September, Atara presented safety and early findings of potential efficacy from a Phase 1a study of ATA188 in patients with progressive MS at the 35th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS)

- Completed enrollment in the fourth and final planned Phase 1 dose escalation cohort
- Atara expects to present additional efficacy and safety results from this study in 2020, including six and twelve-month assessments from cohorts 3 and 4
- Safety results showed across the 4 planned dose cohorts, ATA188 was well tolerated in patients with progressive forms of MS with no evidence of cytokine release syndrome, graft versus host disease or dose-limiting toxicities
- Atara will not initiate a randomized study of autologous ATA190 in progressive MS at this time and will evaluate strategic options for this program
 - Atara's ATA190 portfolio decision is based on continued encouraging ATA188 results, acceleration of the ATA188 randomized Phase 1b study and the Company's strategic focus on off-the-shelf, allogeneic T-cell immunotherapies

ATA2271/ATA3271 and ATA3219 CAR T Programs

- Atara is developing a mesothelin-targeted autologous CAR T (ATA2271) for patients with advanced mesothelioma with an IND planned in 2020
 - ATA2271 is designed using a novel 1XX CAR co-stimulatory domain and PD-1 dominant negative receptor (DNR) intrinsic checkpoint inhibition technology
- Atara is also developing off-the-shelf, allogeneic CAR T immunotherapies targeting mesothelin (ATA3271) and CD19 (ATA3219) using its next generation technologies and EBV T cell platform

Operational

- Facility commissioning and qualification activities to support clinical development at ATOM (Atara T-cell Operations and Manufacturing) are complete
 - Commercial production qualification activities are progressing well and, together with our contracted manufacturing partner, are aligned with our planned commercial strategy
- The Company is focused on aligning the current leadership to the Company's new strategic priorities and actively searching for a new Global Head of Research and Development, Head of Commercial and General Counsel

Third Quarter 2019 Financial Results

- Cash, cash equivalents and short-term investments as of September 30, 2019 totaled \$282.9 million, which includes \$140.7 million in net proceeds from an underwritten public offering completed in July 2019
- The Company believes that its current cash, cash equivalents and short-term investments are sufficient to fund planned operations into 2021
- The Company reported a net loss of \$71.9 million, or \$1.31 per share, for the third quarter of 2019 as compared to \$58.4 million, or \$1.29 per share, for the same period in 2018
- Total operating expenses include non-cash stock-based compensation and depreciation and amortization expenses of \$13.9 million for the third quarter of 2019 as compared to \$10.4 million for the same period in 2018
- Research and development expenses were \$53.5 million for the third quarter of 2019 as compared to \$43.4 million for the same period in 2018. The increase in the third quarter of 2019 was due to costs associated with the Company's continuing expansion of research and development activities, including:

- Clinical study, manufacturing and outside service costs related to our MS programs
- Research and process development costs related to our CAR T programs
- Higher employee-related and overhead costs from increased headcount and operations
- Research and development expenses include \$7.0 million of non-cash stock-based compensation expense for the third quarter of 2019 as compared to \$4.7 million for the same period in 2018
- General and administrative expenses were \$19.0 million for the third quarter of 2019 as compared to \$16.9 million for the same period in 2018. The increase in the third quarter of 2019 was primarily due to increases in employee-related costs driven by increased headcount to support the Company's expanding operations
- General and administrative expenses include \$5.1 million of non-cash stock-based compensation expense for the third quarter of 2019 as compared to \$4.6 million for the same period in 2018

Conference Call and Webcast Information

Atara will host a live conference call and webcast today at 8:00 a.m. EST to discuss the Company's financial results and recent operational highlights. Analysts and investors can participate in the conference call by dialing (888) 540-6216 for domestic callers and (734) 385-2715 for international callers, using the conference ID 6069034. A live audio webcast can be accessed by visiting the Investor Events and Presentations section of atarabio.com. An archived replay will be available on the Company's website for approximately 14 days following the live webcast.

About Atara Biotherapeutics, Inc.

[Atara Biotherapeutics, Inc. \(@Atarabio\)](http://Atarabio) is a leading off-the-shelf, allogeneic T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. Atara's technology platform leverages research collaborations with leading academic institutions with the Company's scientific, clinical, regulatory and manufacturing expertise. Atara's pipeline includes tab-cel[®] (tabelecleucel), which is in Phase 3 development for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (EBV+ PTLD) as well as in earlier stage development for other EBV-associated hematologic malignancies and solid tumors, including nasopharyngeal carcinoma (NPC); T-cell immunotherapies targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis; and next-generation chimeric antigen receptor T-cell (CAR T) immunotherapies. The company was founded in 2012 and is co-located in South San Francisco and Southern California. Our Southern California hub is anchored by the state-of-the-art Atara T-cell Operations and Manufacturing (ATOM) facility in Thousand Oaks, California. For additional information about the company, please visit atarabio.com.

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 benefits and efficacy of Atara Biotherapeutics' drug candidates; the outcome of discussions with regulators, including the EMA; the timing of and the Company's ability to achieve clinical and regulatory milestones, including the timing of CTA and BLA submissions for tab-cel[®] for

patients with EBV+ PTLD, the results from Atara's ongoing tab-cel[®] EAP study and the timing and results of additional data from Atara Biotherapeutics' clinical trials; Atara Biotherapeutics' ability to accelerate the Phase 1b study of ATA188; the outcome of strategic options with respect to ATA190; commercial production qualification activities at ATOM; and the sufficiency of the Company's cash, cash equivalents and short-term investments. These forward-looking statements are subject to risks and uncertainties, including those discussed in Atara Biotherapeutics' filings with the Securities and Exchange Commission (SEC), including in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of the Company's most recently filed periodic reports on Form 10-K and Form 10-Q and subsequent filings and in the documents incorporated by reference therein. 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 BOTHERAPEUTICS, INC.
Consolidated Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 94,431	\$ 60,698
Short-term investments	188,491	248,933
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	10,302	11,664
Total current assets	293,418	321,489
Property and equipment, net	55,697	68,576
Operating lease assets	14,204	—
Restricted cash - long-term	1,200	1,200
Other assets	266	574
Total assets	\$ 364,785	\$ 391,839
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,155	\$ 3,719
Accrued compensation	12,897	10,636
Accrued research and development expenses	6,172	19,210
Other current liabilities	6,482	6,414
Total current liabilities	30,706	39,979
Operating lease liabilities - long-term	14,532	—
Other long-term liabilities	1,105	13,003
Total liabilities	46,343	52,982
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	1,057,669	866,541
Accumulated other comprehensive income (loss)	233	(340)
Accumulated deficit	(739,465)	(527,349)
Total stockholders' equity	318,442	338,857
	\$ 364,785	\$ 391,839

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 53,538	\$ 43,355	\$ 154,457	\$ 105,202
General and administrative	19,018	16,865	61,525	50,093
Total operating expenses	72,556	60,220	215,982	155,295
Loss from operations	(72,556)	(60,220)	(215,982)	(155,295)
Interest and other income, net	661	1,859	3,502	4,611
Loss before provision for income taxes	(71,895)	(58,361)	(212,480)	(150,684)
Provision for income taxes	—	—	—	3
Net loss	\$ (71,895)	\$ (58,361)	\$ (212,480)	\$ (150,687)
Other comprehensive (gain) loss:				
Unrealized gain (loss) on available-for-sale securities	60	56	573	(298)
Comprehensive loss	\$ (71,835)	\$ (58,305)	\$ (211,907)	\$ (150,985)
Net loss per common share:				
Basic and diluted net loss per common share	\$ (1.31)	\$ (1.29)	\$ (4.32)	\$ (3.49)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	54,920	45,406	49,176	43,148

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Source: Atara Biotherapeutics, Inc.