

# Atara Biotherapeutics Announces Third Quarter 2018 Financial Results and Recent Operational Progress

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2018 (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 2018 and recent operational progress.

"We made important progress in the third quarter advancing our off-the-shelf, allogeneic T-cell immunotherapy pipeline," said Isaac Ciechanover, M.D., Chief Executive Officer and President of Atara Biotherapeutics. "We recently announced a strategic collaboration with Moffitt Cancer Center to expand our next-generation CAR T immunotherapy pipeline and initiated a Phase 1/2 clinical study of tab-cel<sup>®</sup> in combination with Merck's KEYTRUDA<sup>®</sup> for patients with EBV-associated nasopharyngeal carcinoma. This is an exciting period for Atara and we look forward to updating you on additional pipeline results at the ASH and ESMO IO scientific congresses in December."

Atara continues to advance its tab-ce<sup>®</sup> (tabelecleucel) Phase 3 studies for patients with Epstein-Barr virus associated post-transplant lymphoproliferative disorder (EBV+ PTLD) and anticipates initial tab-cel<sup>®</sup> Phase 3 results in the first half of 2019. The Company is in ongoing discussions with the European Medicines Agency (EMA) and U.S. Food & Drug Administration (FDA) regarding the development and regulatory paths for tab-cel<sup>®</sup> based on its experience conducting the Phase 3 studies in patients with this life-threatening condition. The Company plans to share initial Phase 3 clinical results as well as observed EBV+ PTLD incidence with these agencies. The outcomes of both regulatory discussions are expected in the first half of 2019, and Atara now plans to submit a tab-cel<sup>®</sup> EU conditional marketing authorization (CMA) application in the second half of 2019.

Atara continues to build its pipeline and operational capabilities as well as prepare for the launch of its first commercial product. Initial results from the off-the-shelf, allogeneic ATA188 multiple sclerosis program are anticipated in the first half of 2019. In addition, the Company is rapidly advancing its next-generation chimeric antigen receptor T-cell (CAR T) pipeline across multiple therapeutic areas and expects to highlight results at upcoming events.

# **Recent Highlights and Anticipated Upcoming Milestones**

Tab-cel® (tabelecleucel)

• Two Phase 3 clinical studies are ongoing (MATCH and ALLELE) to evaluate tab-cell (tabelecleucel) for patients with EBV+ PTLD who have failed rituximab following hematopoietic cell transplant (HCT) or solid organ transplant (SOT).

- Expanded MATCH and ALLELE study sites with 26 locations available for enrollment in the United States and Australia with additional sites expected to open in the United States and other geographies.
- Initiated a Phase 1/2 clinical study of tab-ce<sup>®</sup> in combination with Merck's anti-PD-1 (programmed death receptor-1) therapy, KEYTRUDA<sup>®</sup> (pembrolizumab), in patients with platinum-resistant or recurrent EBV-associated nasopharyngeal carcinoma (NPC).
- Scheduled to present new tab-cel<sup>®</sup> efficacy and safety results in patients with EBV-associated leiomyosarcoma (EBV+ LMS) solid tumors at the European Society for Medical Oncology (ESMO) Immuno-Oncology Congress in December 2018.

# 60th American Society of Hematology (ASH) Annual Meeting

- Announced eight abstracts highlighting robust off-the-shelf, allogeneic T-cell immunotherapy pipeline and next-generation CAR T technologies to be presented at the 60th ASH Annual Meeting in December 2018.
  - Moffitt Cancer Center collaborators to present next-generation CAR T technology that increases T cell persistence and decreases exhaustion.
  - Memorial Sloan Kettering (MSK) collaborators to present tab-ce<sup>®</sup> Phase 2 clinical results for patients with EBV+ PTLD involving the central nervous system (CNS).
  - Current PTLD patient health outcomes and treatment patterns are described in additional ASH abstracts.

# Next-Generation CAR T Development Pipeline

- Announced a strategic collaboration with Moffitt Cancer Center to develop multitargeted CAR T immunotherapies for patients with AML and B cell malignancies.
  - Along with prior CAR T collaboration with MSK, furthers Atara's strategy to develop next-generation CAR T immunotherapies across multiple therapeutic areas and leverage the Company's off-the-shelf, allogeneic T-cell immunotherapy platform.
  - Research supporting the novel CAR T co-stimulatory domain findings were recently published in the September 2018 issue of the *Journal of Clinical Investigation*.
  - CAR T preclinical activities ongoing, with initial IND expected Q4 2019 to Q1 2020.
- Hosting CAR T Breakfast Teach-In on November 29, 2018 in New York, NY focused on Atara's next-generation CAR T immunotherapy pipeline for patients with hematologic and solid tumors, autoimmune and infectious diseases as well as off-the-shelf, allogeneic CAR T development using EBV-specific T cell platform.
  - Featured experts: Michel Sadelain, M.D., Ph.D., MSK and Marco Davila, M.D., Ph.D., Moffitt Cancer Center.

# ATA188 & ATA190 for Multiple Sclerosis (MS)

- A Phase 1 clinical study to evaluate off-the-shelf, allogeneic ATA188 in patients with progressive MS is underway across clinical sites in the United States and Australia.
  - Initial results from the ongoing study are expected in the first half of 2019.
- Plan to initiate a randomized autologous ATA190 study in progressive MS patients in

#### Other Pipeline

 Recent positive published results support Atara's continued development of ATA621, targeting both JC and BK viruses for patients with progressive multifocal leukoencephalopathy (PML). The Company is currently conducting IND enabling manufacturing process development for this program.

# Corporate

- Strengthened the Company's Board of Directors with the appointment of Roy Baynes, M.D., Ph.D. Dr. Baynes currently serves as Senior Vice President Global Clinical Development and Chief Medical Officer at Merck Research Laboratories.
- Additional appointments include the promotion of Manher (AJ) Joshi, M.D., to Chief Medical Officer, the appointment of Renu Vaish as Atara's Senior Vice President, Global Regulatory Affairs, as well as Jose Vidal's appointment as Atara's Senior Vice President, Head of GMP Quality and Process Sciences.
- Continued to increase manufacturing activities at Atara T Cell Operations & Manufacturing (ATOM) facility with completion of licensure to support clinical production expected in 2019.

#### **Third Quarter 2018 Financial Results**

- Cash, cash equivalents and short-term investments as of September 30, 2018 totaled \$364.5 million, which the Company believes will fund planned operations to mid-2020.
- The Company reported net losses of \$58.4 million, or \$1.29 per share, for the third quarter of 2018, as compared to \$31.1 million, or \$1.02 per share, for the same period in 2017.
- In the third quarters of 2018 and 2017, total operating expenses of \$60.2 million and \$31.7 million included non-cash expenses of \$10.4 million and \$6.3 million, respectively.
- Research and development expenses were \$43.4 million for the third quarter of 2018, as compared to \$20.6 million for the same period in 2017. The increase in the third quarter of 2018 was due to costs associated with the Company's continuing expansion of research and development activities, including:
  - clinical trial, manufacturing and outside service costs related to the two Phase 3 clinical trials of tab-cel<sup>®</sup> in patients with EBV+ PTLD and the Phase 1 clinical trial of allogeneic ATA188 in patients with MS, and
  - higher employee-related and overhead costs from increased headcount and operations.
- Research and development expenses include \$4.7 million and \$2.1 million of non-cash stock-based compensation expenses in the third quarters of 2018 and 2017, respectively.

General and administrative expenses were \$16.9 million for the third quarter of 2018, as compared to \$11.1 million for the same period in 2017. The increase in the third quarter of 2018 was primarily due to increases in professional services costs and employee-related costs from increased headcount to support the Company's expanding operations. General and administrative expenses include \$4.6 million and \$3.9 million of non-cash stock-based compensation expenses in the third quarters of 2018 and 2017, respectively.

# Atara Biotherapeutics, Inc. Condensed Consolidated Balance Sheets (Unaudited) (In thousands)

	September 30,		December 31,			
	2018			2017		
Assets	<u></u>		-			
Current assets:						
Cash and cash equivalents	\$	66,028	\$	79,223		
Short-term investments		298,515		86,873		
Restricted cash - short-term		194		194		
Prepaid expenses and other current assets			5,900			
Total current assets		372,976		172,190		
Property and equipment, net		44,129				
Restricted cash - long-term		1,200				
Other assets		485		260		
Total assets	\$	442,940	\$	217,779		
Liabilities and stockholders' equity						
Current liabilities:						
Accounts payable	\$	6,193	\$	14,711		
Accrued compensation		9,072		5,664		
Accrued research and development expenses		3,803		4,006		
Other current liabilities		7,932		3,265		
Total current liabilities		27,000		27,646		
Long-term liabilities		12,886		12,269		
Total liabilities		39,886		39,915		
Commitments and contingencies						
Stockholders' equity:						
Common stock		5		3		
Additional paid-in capital		850,835		474,662		
Accumulated other comprehensive loss		(449 )		(151 )		
Accumulated deficit		(447,337)		(296,650)		
Total stockholders' equity		403,054		177,864		
Total liabilities and stockholders' equity	\$	442,940	\$	217,779		

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,				
		2018		2017		2018		2017
Operating expenses:						_		
Research and development	\$	43,355	\$	20,598	\$	105,202	\$	56,435
General and administrative		16,865		11,062		50,093		29,295
Total operating expenses		60,220		31,660		155,295		85,730
Loss from operations		(60,220)		(31,660)		(155,295)		(85,730 )
Interest and other income, net		1,859		564		4,611		1,554
Loss before provision for income taxes		(58,361)		(31,096)		(150,684)		(84,176)
Provision for income taxes		_		_		3		2
Net loss	\$	(58,361)	\$	(31,096)	\$	(150,687)	\$	(84,178)
Other comprehensive loss:								
Unrealized gain (loss) on available-for-sale								
securities		56		26		(298)		95
Comprehensive loss	\$	(58,305)	\$	(31,070)	\$	(150,985)	\$	(84,083)
Net loss per common share:								
Basic and diluted net loss per common share	\$	(1.29)	\$	(1.02)	\$	(3.49)	\$	(2.84)
Weighted-average shares outstanding used								
to calculate basic and diluted net loss per common								
share		45,406		30,474	_	43,148	_	29,597

Nine Months Ended Sentembe

# About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. (@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 most advanced T-cell immunotherapy, tab-cel<sup>®</sup> (tabelecleucel), is in Phase 3 development for patients with Epstein-Barr virus associated post-transplant lymphoproliferative disorder (EBV+ PTLD), as well as other EBV associated hematologic and solid tumors, including nasopharyngeal carcinoma (NPC). Atara is also developing T-cell immunotherapies targeting EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). Atara's pipeline also includes next generation chimeric antigen receptor T-cell (CAR T) immunotherapies for patients with hematologic and solid tumors, autoimmune and viral diseases. The company was founded in 2012 and is headquartered in South San Francisco, California.

# **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 ability to expand its pipeline; the timing and results of the Company's Phase 1/2 study of tab-cel<sup>®</sup> in combination with Merck's KEYTRUDA<sup>®</sup> (pembrolizumab) in patients with platinum-resistant or recurrent EBV-associated NPC; the results and timing of its tab-cel<sup>®</sup> Phase 3 studies; the Company's plans to share clinical results and disease incidence with regulatory authorities, including the associated timing; the timing of the Company's submission of a conditional market authorization application for tab-cel<sup>®</sup> in the EU; enrollment of patients in the Company's clinical trials; opening additional clinical sites in the United States and other geographies; the Company's ability to develop next-generation CAR T immunotherapies across multiple therapeutic areas; the timing of the Company's initial CAR T IND; the timing and results of the Company's Phase 1 studies of ATA 188 and ATA190 in patients with progressive MS; the Company's ability to develop ATA621 targeting JC and BK viruses and develop IND-enabling processes for this candidate;

the sufficiency of the Company's cash, cash equivalents and short-term investments to fund operations to mid-2020; the Company's ability to leverage its platform in other indications and initiate development of additional immunotherapies; and the potential advantages of its product candidates. 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 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.

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