

# Atara Biotherapeutics Announces Fourth Quarter and Full Year 2019 Financial Results and Recent Clinical, Operational and Strategic Progress

## Company to host conference call today at 8:00 a.m. EST

SOUTH SAN FRANCISCO, Calif., Feb. 27, 2020 (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 fourth quarter and full year ended December 31, 2019 and recent business highlights.

“2019 was a year of strategic prioritization and significant advancement of our T-cell immunotherapy programs,” said Pascal Touchon, President and Chief Executive Officer of Atara. “In 2020 we plan to deliver on key milestones across our pipeline and further establish Atara as a leader in off-the-shelf, allogeneic T-cell immunotherapies through our innovative EBV T-cell platform, next-generation CAR T technologies and state-of-the-art manufacturing capabilities. This work underpins our mission to transform the lives of patients with serious medical conditions through pioneering science, teamwork and a commitment to excellence.”

## Recent Highlights and Anticipated Upcoming Milestones

### **Tab-cel® (tabelecleucel)**

- Atara continues to progress tab-cel® Phase 3 development for patients with Epstein-Barr virus-associated post-transplant lymphoproliferative disease (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
  - Atara plans to discuss the totality of tab-cel® results with the U.S. Food and Drug Administration (FDA) in a pre-BLA meeting prior to initiating the BLA submission
  - In the U.S. and Australia, 38 sites are available for enrollment and the Company is preparing to open additional sites in the U.S., Canada and Europe
  - Atara submitted clinical trial applications (CTAs) to several European countries in November and December 2019 to enable the opening of EU clinical sites in 2020. The Company's CTAs in the United Kingdom, Spain and Austria were recently approved
- Atara recently submitted a Pediatric Investigation Plan (PIP) to the European Medicines Agency (EMA)
  - Following EMA approval of the PIP, Atara plans to submit a tab-cel® EU marketing authorization application for patients with EBV+ PTLD in 2021
- Atara continues to see strong tab-cel® investigator, physician and patient interest and, for cases in which the Company is not able to enroll patients in its EBV+ PTLD Phase 3 clinical study, Atara is providing tab-cel® to patients in need under its expanded access protocol (EAP) and single patient use (SPU) programs
  - In December 2019, Atara presented long-term clinical results for 61 patients with diverse EBV-associated diseases, including efficacy and safety data for 26 patients with relapsed/refractory EBV+ PTLD and safety findings for 35 patients with other EBV-associated diseases, from a multicenter EAP study of tab-cel® at the 61<sup>st</sup> American Society of Hematology (ASH) Annual Meeting & Exposition
    - Results from this analysis suggest a high overall response rate (ORR), short time to response and favorable estimated long-term overall survival (OS) rates for tab-cel® in patients with EBV+ PTLD following hematopoietic cell transplant (HCT) or solid organ transplant (SOT) who have failed rituximab-based therapy
    - Tab-cel® was shown to be generally well-tolerated in all patients with EBV+ PTLD and other EBV-associated diseases
- Studies supporting potential additional tab-cel® indications are also advancing
  - Atara expects to initiate enrollment in a tab-cel® Phase 2 multi-cohort study including up to six additional ultra-rare EBV+ diseases in the second half of 2020 based on previous clinical data treating these patients

- Atara enrolled the final planned patient in the Phase 1b portion of a Phase 1b/2 clinical study of tab-cel<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)

### **ATA188 for Progressive Multiple Sclerosis (MS)**

- A Phase 1a clinical study of off-the-shelf, allogeneic ATA188 in patients with progressive MS is ongoing across clinical sites in the U.S. and Australia
  - Atara expects to present six- and 12-month ATA188 Phase 1a clinical results for cohorts 3 and 4 in the first and second halves of 2020, respectively
  - Atara retreated the first patients in the open label extension (OLE) portion of the Phase 1a study; OLE design allows patients who complete one year in the Phase 1a dose-escalation portion of the study to be retreated annually using the cohort 3 dose for up to four years
- Atara plans to initiate enrollment of a randomized, double-blind, placebo-controlled Phase 1b study in patients with progressive MS in the second or third quarter of 2020
  - Activation of clinical study sites for the Phase 1b is ongoing with an increased number of leading MS centers expected to participate in the U.S. and Australia

### **EBV CAR T Platform**

- In February 2020, an academic off-the-shelf, allogeneic CD19 CAR T clinical study using an EBV T-cell construct for patients with relapsed/refractory B-cell malignancies was presented at the 2020 Transplantation and Cellular Therapy (TCT) Meetings
  - No cytokine release syndrome or neurotoxicity above Grade 2, and dose-limiting toxicities were observed post-infusion with multiple EBV CD19 CAR T doses administered
    - No confirmed GvHD was observed in patients who received partially HLA matched third-party donor EBV CD19 CART cells
  - Investigators observed durable complete responses (CR) with median follow up of 26.9 months for 83 percent (5/6) of patients who received partially HLA matched EBV CD19 CAR T cells manufactured from third-party donors including
    - 100 percent (4/4) response in patients with non-Hodgkin's lymphoma (NHL)
    - 100 percent (1/1) response in patient with chronic lymphocytic leukemia (CLL)
- Findings from this study provide initial clinical proof-of-principle that an EBV T-cell platform has the potential to generate off-the-shelf, allogeneic CAR T immunotherapies with high and durable responses, low risk of toxicity and that can be rapidly delivered to patients

### **ATA2271/ATA3271 and ATA3219 CAR T Programs**

- Atara is developing a mesothelin-targeted autologous CAR T (ATA2271) and expects collaborators at Memorial Sloan Kettering Cancer Center (MSK) to submit an Investigational New Drug (IND) application to the FDA for patients with advanced mesothelioma in the second or third quarter of 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
  - Started preclinical IND-enabling studies for ATA3219 and ATA3271

### **Operational**

- Atara named Kristin Yarema as Chief Commercial Officer; Dr. Yarema brings extensive hematology, oncology, neuroscience and autoimmune disease commercialization experience to Atara as the Company advances commercialization activities for tab-cel<sup>®</sup>
- Atara created a Chief Operations Officer role to continue to drive operational excellence across the Company's programs and platform; Joe Newell, Atara's current Chief Technical Operations Officer, was appointed to this new role
- Atara is executing on its planned commercial supply strategy with continued positive progress on commercial production qualification activities with the Company's contract manufacturing partner and dedicated, state-of-the-art T cell manufacturing facility in Thousand Oaks, Calif.
- Atara continues to scale its EBV T-cell manufacturing platform with current yields of approximately 400 tab-cel<sup>®</sup> doses from a single donor leukapheresis

## Fourth Quarter and Full Year 2019 Financial Results

- Atara believes that its cash, cash equivalents and short-term investments as of December 31, 2019, together with the net proceeds from the “at-the-market” (ATM) facility in January 2020, are sufficient to fund planned operations into the second quarter of 2021
  - Cash, cash equivalents and short-term investments as of December 31, 2019 totaled \$259.1 million, as compared to \$282.9 million as of September 30, 2019
  - Net cash used in operating activities was \$58.7 million and \$235.6 million for the fourth quarter and fiscal year 2019, respectively, as compared to \$57.4 million and \$179.8 million for the same periods in 2018
  - In the fourth quarter of 2019, the Company sold 2,449,216 shares of common stock pursuant to its ATM facility for net proceeds of \$36.3 million and in January 2020 sold 1,371,216 shares of common stock for net proceeds of \$21.1 million
  - Proforma cash, cash equivalents and short-term investments as of December 31, 2019, including aggregate ATM and option exercise proceeds of \$23.6 million in January 2020, was \$282.7 million. The number of outstanding shares of common stock and pre-funded common stock warrants as of February 18, 2020 were 58,571,550 shares and 2,888,526 warrants, respectively
- Atara reported net losses of \$78.5 million, or \$1.36 per share, and \$291.0 million, or \$5.67 per share, for the fourth quarter and fiscal year 2019, respectively, as compared to \$80.0 million, or \$1.75 per share, and \$230.7 million, or \$5.27 per share, for the same periods in 2018
- Total operating expenses include non-cash expenses of \$14.0 million and \$58.8 million for the fourth quarter and fiscal year 2019, respectively, as compared to \$11.0 million and \$37.5 million for the same periods in 2018
- Research and development expenses were \$61.6 million and \$216.1 million for the fourth quarter and fiscal year 2019, respectively, as compared to \$62.3 million and \$167.5 million for the same periods in 2018
  - The decrease in the fourth quarter 2019 was primarily due to one-time license fees of \$12.5 million incurred in the fourth quarter of 2018 for exclusive rights to the next-generation CAR T program targeting mesothelin, with no such corresponding costs incurred in fourth quarter of 2019, partially offset by higher employee-related and overhead costs from increased headcount and operating activities
  - The increase in fiscal year 2019 was primarily 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 MS programs
    - Research and process development costs related to CAR T programs
    - Higher employee-related and overhead costs from increased headcount and operating activities
- Research and development expenses include \$7.0 million and \$26.8 million of non-cash stock-based compensation expenses for the fourth quarter and fiscal year 2019, respectively, as compared to \$5.2 million and \$16.2 million for the same periods in 2018
- General and administrative expenses were \$18.1 million and \$79.6 million for the fourth quarter and fiscal year 2019, respectively, as compared to \$19.6 million and \$69.7 million for the same periods in 2018. The decrease in the fourth quarter 2019 was primarily due to a decrease in outside services costs, partially offset by an increase in employee-related costs driven by increased headcount. The increase in the fiscal year 2019 was primarily due to an increase in employee-related costs driven by increased headcount to support the Company’s expanding operations
- General and administrative expenses include \$5.0 million and \$24.9 million of non-cash stock-based compensation expenses for the fourth quarter and fiscal year 2019, respectively, as compared to \$4.3 million and \$17.6 million for the same periods 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 1554668. A live audio webcast can be accessed by visiting the [Investors & Media – News & Events](#) 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. \(@Atarabio\)](#) 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 our state-of-the-art manufacturing facility in Thousand Oaks, California. For additional information about the Company, please visit [atarabio.com](http://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's drug candidates; Atara's ability to deliver on key milestones in 2020; the outcome of discussions with regulators, including discussions with the EMA on Atara's recently-submitted PIP; the timing of and the Company's ability to achieve clinical and regulatory milestones, including the timing of BLA submissions for tab-cel<sup>®</sup> for patients with EBV+ PTLD, the results from Atara's ongoing tab-cel<sup>®</sup> EAP study, enrollment of patients in in a tab-cel<sup>®</sup> Phase 2 multi-cohort study, and the timing and results of additional data from Atara's clinical trials; Atara's ability to open EU clinical sites in 2020 for its Phase 3 trial of for tab-cel<sup>®</sup> for patients with EBV+ PTLD; and the sufficiency of the Company's cash, cash equivalents and short-term investments and ATM proceeds. These forward-looking statements are subject to risks and uncertainties, including those discussed in Atara's 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 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)

	December 31, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 74,317	\$ 60,698
Short-term investments	184,792	248,933
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	13,689	11,664
Total current assets	272,992	321,489
Property and equipment, net	54,176	68,576
Operating lease assets	14,007	—
Restricted cash - long-term	1,200	1,200
Other assets	567	574
Total assets	\$ 342,942	\$ 391,839
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 7,963	\$ 3,719
Accrued compensation	14,706	10,636
Accrued research and development expenses	8,341	19,210
Other current liabilities	5,733	6,414
Total current liabilities	36,743	39,979
Operating lease liabilities - long-term	14,136	—
Other long-term liabilities	1,282	13,003
Total liabilities	52,161	52,982
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock	6	5
Additional paid-in capital	1,108,516	866,541
Accumulated other comprehensive income (loss)	220	(340)
Accumulated deficit	(817,961)	(527,349)

Total stockholders' equity	290,781	338,857
Total liabilities and stockholders' equity	<u>\$ 342,942</u>	<u>\$ 391,839</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,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 61,640	\$ 62,255	\$ 216,097	\$ 167,457
General and administrative	18,059	19,561	79,584	69,654
Total operating expenses	<u>79,699</u>	<u>81,816</u>	<u>295,681</u>	<u>237,111</u>
Loss from operations	(79,699 )	(81,816 )	(295,681 )	(237,111 )
Interest and other income, net	1,215	1,757	4,717	6,368
Loss before income taxes	(78,484 )	(80,059 )	(290,964 )	(230,743 )
Provision for (benefit from) income taxes	12	(47 )	12	(44 )
Net loss	(78,496 )	\$ (80,012 )	\$ (290,976 )	\$ (230,699 )
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	(13 )	109	560	(189 )
Comprehensive loss	<u>\$ (78,509 )</u>	<u>\$ (79,903 )</u>	<u>\$ (290,416 )</u>	<u>\$ (230,888 )</u>
Net loss per common share:				
Basic and diluted net loss per common share	<u>\$ (1.36 )</u>	<u>\$ (1.75 )</u>	<u>\$ (5.67 )</u>	<u>\$ (5.27 )</u>
 Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	 <u>57,662</u>	 <u>45,777</u>	 <u>51,308</u>	 <u>43,811</u>

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Source: Atara Biotherapeutics, Inc.