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Atara Biotherapeutics Announces Fourth Quarter and Full Year 2018 Financial Results and Recent Operational Progress

SOUTH SAN FRANCISCO, Calif., Feb. 26, 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 fourth quarter and full year ended December 31, 2018, and recent operational highlights.

“2018 was a year of pipeline expansion and strong operational execution for Atara as we advanced our T-cell immunotherapy programs across all three of our major value drivers: tab-cel[®], multiple sclerosis and next-generation CAR T,” said Isaac Ciechanover M.D., Chief Executive Officer and President of Atara Biotherapeutics. “Notably, we successfully executed on our strategy to build a leading next-generation and off-the-shelf, allogeneic CAR T portfolio. Our collaborations with academic leaders leverage technologies at the forefront of CAR T innovation for hematologic malignancies and solid tumors. We also opened a state-of-the-art T-cell operations and manufacturing facility and expanded our R&D, operational and commercial leadership. I am extremely gratified with where the Company is today and wish to acknowledge the many extraordinary contributions by Atara employees that enabled us to reach this point. I anticipate 2019 to be another pivotal year with multiple clinical and regulatory milestones, moving Atara closer to realizing our mission of transforming the lives of patients with serious medical conditions.”

Atara continues to progress tab-cel[®] (tabelecleucel) Phase 3 studies for patients with Epstein-Barr virus associated post-transplant lymphoproliferative disease (EBV+ PTLD) and anticipates initial tab-cel[®] Phase 3 results to be available to the company in the first half of 2019.

Discussions with the European Medicines Agency (EMA) and U.S. Food & Drug Administration (FDA) regarding the development of tab-cel[®] are ongoing and Atara’s intention is to align on a global regulatory strategy for patients with EBV+ PTLD. Outcomes of these discussions are expected in the first half of 2019.

Atara plans to submit a tab-cel[®] EU conditional marketing authorization (CMA) application in the second half of 2019. To ensure the integrity of the ongoing, open-label tab-cel[®] Phase 3 studies, the Company anticipates disclosing initial top-line EBV+ PTLD results in the second half of 2019 following submission of the EMA CMA application.

Atara expects initial safety results from the ongoing off-the-shelf, allogeneic ATA188 Phase 1 study in patients with progressive multiple sclerosis (MS) in the first half of 2019. Additional safety and efficacy results from this study are expected in the second half of 2019.

The Company is also rapidly advancing its next-generation chimeric antigen receptor T-cell (CAR T) pipeline across multiple therapeutic areas and expects results to be presented at upcoming scientific conferences.

Recent Highlights and Anticipated Upcoming Milestones

Tab-cel[®] (tabelecleucel)

- Two Phase 3 clinical studies are ongoing (MATCH and ALLELE) to evaluate tab-cel[®] 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 30 sites available for enrollment in the United States and Australia, and with additional sites expected to open in the United States and other geographies.

ATA188 & ATA190 for Multiple Sclerosis (MS)

- A Phase 1 clinical study of off-the-shelf, allogeneic ATA188 in patients with progressive MS is ongoing across clinical sites in the United States and Australia.
- Atara also plans to initiate a randomized autologous ATA190 study in progressive MS patients in the second half of 2019.

Next-Generation CAR T Development Pipeline

- Licensed worldwide rights to a mesothelin-targeted chimeric antigen receptor T-cell (CAR T) immunotherapy for solid tumors from Memorial Sloan Kettering Cancer Center (MSK).
 - Development with MSK will focus on a next-generation, mesothelin-targeted CAR T using novel 1XX CAR signaling domain and PD-1 dominant negative receptor (DNR) checkpoint inhibition technologies for patients with mesothelin-associated solid tumors.
- Expect clinical and preclinical results supporting Atara's next-generation CAR T programs to be presented at the American Association of Cancer Research (AACR) Annual Meeting 2019 to be held March 29 to April 3 in Atlanta, Georgia.
- First IND submission for Atara's next-generation CAR T program expected in the fourth quarter of 2019 or first quarter of 2020.

Other Pipeline

- Conducting IND-enabling manufacturing process development for ATA621, targeting both JC and BK viruses for patients with progressive multifocal leukoencephalopathy (PML).

Corporate

- Atara's Board of Directors is currently conducting a search for a new Chief Executive Officer following Dr. Ciechanover's transition plan announced in January. Dr. Ciechanover will remain in his role as President and CEO until the earlier of the appointment of his successor or June 30, 2019.

Fourth Quarter and Full Year 2018 Financial Results

- Cash, cash equivalents and short-term investments as of December 31, 2018 totaled \$309.6 million, which we believe will be sufficient to fund planned operations to mid-2020. The balance excludes the impact of one-time license fees of \$12.5 million paid in the first quarter of 2019 for worldwide rights to the next-generation allogeneic CAR T program targeting mesothelin.
- The Company reported net losses of \$80.0 million, or \$1.75 per share, and \$230.7 million, or \$5.27 per share, for the fourth quarter and fiscal year 2018, respectively, as compared to \$35.3 million, or \$1.15 per share, and \$119.5 million, or \$4.00 per share, for the same periods in 2017.
- Total operating expenses include total non-cash expenses of \$11.0 million and \$37.5 million for the fourth quarter and fiscal year 2018, respectively, as compared to \$6.4 million and \$24.1 for the same periods in 2017.
- Research and development expenses were \$62.3 million and \$167.5 million for the fourth quarter and fiscal year 2018, respectively, as compared to \$24.8 million and \$81.2 million for the same periods in 2017. The increases in the fourth quarter and fiscal year 2018 were 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 the two Phase 3 clinical studies of tab-cel[®] in patients with EBV+ PTLD and the Phase 1 clinical study of allogeneic ATA188 in patients with progressive MS;
 - one-time license fees of \$12.5 million incurred in the fourth quarter of 2018 for exclusive rights to a next-generation allogeneic CAR T program targeting mesothelin from MSK;
 - higher employee-related and overhead costs from increased headcount and operations, and
 - an increase in facilities and information technology expenses that are allocated to our research and development function.
- Research and development expenses include \$5.2 million and \$16.2 million of non-cash stock-based compensation expenses for the fourth quarter and fiscal year 2018, respectively, as compared to \$2.5 million and \$8.8 million for the same periods in 2017.
- General and administrative expenses were \$19.6 million and \$69.7 million for the fourth quarter and fiscal year 2018, respectively, as compared to \$11.0 million and \$40.3 million for the same periods in 2017. The increases in the fourth quarter and fiscal year 2018 were primarily due to increases in professional services costs and employee-related costs driven by increased headcount to support the Company's expanding operations.
- General and administrative expenses include \$4.3 million and \$17.6 million of non-cash stock-based compensation expenses for the fourth quarter and fiscal year 2018, respectively, as compared to \$3.6 million and \$14.3 million for the same periods in 2017.

ATARA BIOTHERAPEUTICS, INC.
Consolidated Balance Sheets
(Unaudited)
(In thousands)

	December 31,	December 31,
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 60,698	\$ 79,223
Short-term investments	248,933	86,873
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	11,664	5,900
Total current assets	321,489	172,190
Property and equipment, net	68,576	44,129
Restricted cash - long-term	1,200	1,200
Other assets	574	260
Total assets	\$ 391,839	\$ 217,779
 Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,719	\$ 14,711
Accrued compensation	10,636	5,664
Accrued research and development expenses	19,210	4,006
Other current liabilities	6,414	3,265
Total current liabilities	39,979	27,646
Long-term liabilities	13,003	12,269
Total liabilities	52,982	39,915
 Commitments and contingencies		
 Stockholders' equity:		
Common stock	5	3
Additional paid-in capital	866,541	474,662
Accumulated other comprehensive loss	(340)	(151)
Accumulated deficit	(527,349)	(296,650)
Total stockholders' equity	338,857	177,864
Total liabilities and stockholders' equity	\$ 391,839	\$ 217,779

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,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 62,255	\$ 24,771	\$ 167,457	\$ 81,206
General and administrative	19,561	11,031	69,654	40,326
Total operating expenses	81,816	35,802	237,111	121,532
Loss from operations	(81,816)	(35,802)	(237,111)	(121,532)
Interest and other income, net	1,757	473	6,368	2,027
Loss before income taxes	(80,059)	(35,329)	(230,743)	(119,505)
Benefit from income taxes	(47)	(16)	(44)	(14)
Net loss	\$ (80,012)	\$ (35,313)	\$ (230,699)	\$ (119,491)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	109	(63)	(189)	32
Comprehensive loss	\$ (79,903)	\$ (35,376)	\$ (230,888)	\$ (119,459)
Net loss per common share:				
Basic and diluted net loss per common share	\$ (1.75)	\$ (1.15)	\$ (5.27)	\$ (4.00)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	45,777	30,651	43,811	29,863

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 disorder (EBV+ PTLTD) as well as 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 for cancer as well as targets in other therapeutic areas. 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.

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 achieve clinical and regulatory milestones in 2019; tab-cel[®] Phase 3 results; discussions with the EMA and FDA; the Company's plans to submit a tab-cel[®] CMA application; results from the ATA188 Phase 1 study; the Company's ability to rapidly advance its CAR T pipeline and for related results to be presented; opening additional clinical sites in the United States and other geographies; the Company's plans to initiate an ATA190 study; the Company's plans to submit an IND related to its next-generation CAR T program and the timing thereof; the Company's ability to develop ATA621 targeting JC and BK viruses and develop IND-enabling manufacturing processes for this candidate; and the sufficiency of the Company's cash, cash equivalents and short-term investments to fund operations to mid-2020. 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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