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Atara Biotherapeutics Announces First Quarter 2019 Financial Results and Recent Operational Progress

SOUTH SAN FRANCISCO, Calif., May 09, 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 first quarter of 2019 and recent operational highlights.

“We have made important progress advancing our T-cell immunotherapy programs across our three 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. “Discussions with EMA and FDA to align on a tab-cel[®] global regulatory strategy for patients with Epstein-Barr virus associated post-transplant lymphoproliferative disease are progressing, with outcomes of these discussions expected in the first half of 2019. We are also looking forward to upcoming clinical milestones for our off-the-shelf, allogeneic ATA188 Phase 1 program in progressive multiple sclerosis with initial safety and efficacy results expected this year. In addition, recent clinical results presented by our MSK collaborators reaffirm mesothelin as a promising target for patients with advanced mesothelioma and establish an important proof-of-concept advance for CAR T immunotherapy in solid tumors.”

Atara continues to progress tab-cel[®] (tabelecleucel) Phase 3 studies for patients with Epstein-Barr virus associated post-transplant lymphoproliferative disease (EBV+ PTLD), with enrollment proceeding slower than anticipated. The Company is in discussions with the European Medicines Agency (EMA) and U.S. Food & Drug Administration (FDA) regarding the development of tab-cel[®] and Atara’s intention is to align on a global regulatory strategy for patients with EBV+ PTLD. Atara now plans to submit a tab-cel[®] EU conditional marketing authorization (CMA) application based on initial Phase 3 results in 2020. To ensure the integrity of the ongoing, open-label tab-cel[®] Phase 3 study, the Company anticipates disclosing initial top-line EBV+ PTLD results following acceptance of the EMA CMA application.

“Global regulators recognize the critical need of new therapies to treat patients with EBV+ PTLD,” said Dietmar Berger, M.D., Ph.D., Global Head of Research and Development of Atara Biotherapeutics. “We look forward to our continued discussions with the FDA under Breakthrough Therapy Designation and EMA based on the Priority Medicines (PRIME) regulatory pathway to bring tab-cel[®] to patients with this often life-threatening disease as expeditiously as possible.”

The Company is also advancing an off-the-shelf, allogeneic ATA188 Phase 1 study in patients with progressive multiple sclerosis (MS). Initial safety results for this study are

expected to be presented at the 5th Congress of the European Academy of Neurology (EAN) in June 2019. Additional safety and efficacy results from this study are expected to be presented at a scientific congress in the second half of 2019.

Atara's collaborators at Memorial Sloan Kettering Cancer Center (MSK) reported positive Phase 1 clinical results for their mesothelin-targeted CAR T immunotherapy for patients with solid tumors at the American Association of Cancer Research (AACR) Annual Meeting 2019. Efficacy and safety results were presented for patients with malignant pleural mesothelioma who may also have received pembrolizumab and lymphodepleting chemotherapy. Following administration of a novel mesothelin-targeted CAR T, MSK investigators observed a 72% response rate in a subset of these patients. Atara expects additional results from this study to be presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.

Based on these encouraging results, Atara and MSK are advancing development of a next-generation, mesothelin-targeted CAR T immunotherapy using a novel 1XX CAR signaling domain and PD-1 dominant negative receptor (DNR) checkpoint inhibition technologies, with an IND expected in 2020.

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).
 - In the United States and Australia, 32 sites are available for enrollment, with additional sites expected to open in the United States and other geographies.

2019 ASCO Annual Meeting

- Expect presentations highlighting tab-cel[®] and next-generation CAR T immunotherapy technology to be presented at the 2019 ASCO Annual Meeting to be held May 31 to June 4 in Chicago.
 - Oral Presentation: Regional delivery of mesothelin-targeted CAR T cells for pleural cancers: Safety and preliminary efficacy in combination with anti-PD-1 agent. Abstract 2511, S406, Tuesday, June 4, 2019, 8:36 a.m. - 8:48 a.m. CDT.
 - Poster Presentation: Correlation of circulating EBV-targeted cytotoxic T lymphocyte precursors (EBV-CTLp) and clinical response following tabeclucel (tab-cel[®]) infusion in patients with EBV-driven disease. Abstract 2532, Hall A, Saturday, June 1, 2019, 8:00 a.m. - 11:00 a.m. CDT.
 - Poster Presentation: Tabelecleucel in combination with pembrolizumab (Pembro) in platinum-pretreated, recurrent/metastatic Epstein-Barr virus (EBV)-positive nasopharyngeal carcinoma (EBV+ NPC). Abstract TPS6092, Hall A, Saturday, June 1, 2019, 1:15 p.m. - 4:15 p.m. CDT.

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 expects to present initial safety results from this study during at the 5th

Congress of the European Academy of Neurology (EAN) to be held June 29 to July 2 in Oslo, Norway.

- Additional safety and efficacy results from this study are expected to be presented at a scientific congress in the second half of 2019.
- Expect to initiate a randomized study of autologous ATA190 in progressive MS patients during the second half of 2019.

Next-Generation CAR T

- Positive Phase 1 clinical results for MSK's mesothelin-targeted CAR T immunotherapy were recently presented by our MSK collaborators at the AACR Annual Meeting 2019.
- Encouraging safety results and anti-tumor responses observed in combination with a PD-1 checkpoint inhibitor, support Atara's plans to progress development of a next-generation, mesothelin-targeted CAR T immunotherapy using MSK's novel 1XX CAR signaling domain and PD-1 DNR checkpoint inhibition technologies for patients with mesothelin-associated solid tumors.
- Atara plans to prioritize mesothelin CAR T development and anticipates that this program will be the first CAR T program to enter the clinic, with an IND expected in 2020.
- Additional results from ongoing MSK investigator-sponsored mesothelin-targeted CAR T studies are expected to be presented at the 2019 ASCO Annual Meeting.

Corporate

- Atara's Board of Directors is 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.

First Quarter 2019 Financial Results

- Cash, cash equivalents and short-term investments as of March 31, 2019 totaled \$237.5 million, which the Company believes will be sufficient to fund planned operations to mid-2020.
- The Company reported net losses of \$66.3 million, or \$1.44 per share, for the first quarter of 2019 as compared to \$41.4 million, or \$1.05 per share, for the same period in 2018.
- Total operating expenses include total non-cash expenses of \$13.9 million for the first quarter of 2019 as compared to \$7.3 million for the same period in 2018.
- Research and development expenses were \$48.7 million for the first quarter of 2019 as compared to \$28.5 million for the same period in 2018. The increase in the first 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 tab-cel[®] and the Phase 1 clinical study of off-the-shelf, allogeneic ATA188;
 - 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 \$6.1 million of non-cash stock-based compensation expense for the first quarter of 2019 as compared to \$2.9 million for the same period in 2018.
- General and administrative expenses were \$19.2 million for the first quarter of 2019 as compared to \$14.0 million for the same period in 2018. The increase in the first quarter of 2019 was 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 \$6.2 million of non-cash stock-based compensation expense for the first quarter of 2019 as compared to \$4.1 million for the same period in 2018.

Conference Call and Webcast Information

Atara will host a live conference call and webcast today at 8:30 a.m. EDT 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 1956289. 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. \(@Atarabio\)](#) 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+ PTLN) 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 Company's ability to achieve clinical and regulatory milestones in 2019 and 2020; tab-cel[®] Phase 3 enrollment and results; discussions with regulators, including the Company's ability

to align on a tab-cel[®] global regulatory strategy; the Company's plans to submit a tab-ce[®] CMA application; the Company's ability to advance its ATA188 Phase 1 study, achieve related clinical milestones and to present related results; the Company's ability to advance development of a next-generation mesothelin-targeted CAR T therapy and to submit a related IND; the Company's plans to initiate an ATA190 study; 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.

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

	<u>March 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 56,168	\$ 60,698
Short-term investments	181,377	248,933
Restricted cash - short-term	194	194
Prepaid expenses and other current assets	13,091	11,664
Total current assets	<u>250,830</u>	<u>321,489</u>
Property and equipment, net	58,119	68,576
Operating lease assets	14,041	—
Restricted cash - long-term	1,200	1,200
Other assets	536	574
Total assets	<u>\$ 324,726</u>	<u>\$ 391,839</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,168	\$ 3,719
Accrued compensation	7,459	10,636
Accrued research and development expenses	6,194	19,210

Other current liabilities	5,354	6,414
Total current liabilities	25,175	39,979
Operating lease liabilities - long-term	14,437	—
Other long-term liabilities	1,180	13,003
Total liabilities	40,792	52,982
Commitments and contingencies		
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	877,133	866,541
Accumulated other comprehensive gain (loss)	38	(340)
Accumulated deficit	(593,242)	(527,349)
Total stockholders' equity	283,934	338,857
Total liabilities and stockholders' equity	\$ 324,726	\$ 391,839

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

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 48,668	\$ 28,460
General and administrative	19,223	13,992
Total operating expenses	67,891	42,452
Loss from operations	(67,891)	(42,452)
Interest and other income, net	1,634	1,009
Net loss	(66,257)	(41,443)
Unrealized gain (loss) on available-for-sale securities	378	(373)
Comprehensive loss	\$ (65,879)	\$ (41,816)
Net loss per common share:		
Basic and diluted net loss per common share	\$ (1.44)	\$ (1.05)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	46,124	39,596

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Source: Atara Biotherapeutics, Inc.