Atara Biotherapeutics Announces Second Quarter 2018 Financial Results and Recent Operational Progress

August 1, 2018

SOUTH SAN FRANCISCO, Calif., Aug. 01, 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 second quarter of 2018 and recent operational highlights.

“The future of T-cell immunotherapy is both off-the-shelf and across multiple therapeutic areas,” said Isaac Ciechanover, M.D., Chief Executive Officer and President of Atara Biotherapeutics. “During the second quarter, we continued to advance our robust T-cell immunotherapy pipeline, highlighted by our ongoing Phase 3 studies of tab-cel™ in patients with EBV+ PTLD and Phase 1 study of ATA188 in patients with progressive multiple sclerosis. In parallel, we continue to build Atara’s global commercial and operational capabilities in anticipation of the first tab-cel™ Phase 3 results and submission of an EU conditional marketing authorization application in the first half of 2019. We are also preparing to expand our pipeline with the development of the next generation of chimeric antigen receptor T cell (CAR T) technologies. This is an exciting time for Atara as we enter the next phase of the Company’s growth as a leader in off-the-shelf, allogeneic T-cell immunotherapy.”

Recent Highlights and Anticipated Upcoming Milestones

Tab-cel™ (tabelecleucel)

- Two Phase 3 clinical studies are ongoing (MATCH and ALLELE) to evaluate tab-cel™ (tabelecleucel) in patients with Epstein-Barr virus associated post-transplant lymphoproliferative disorder (EBV+ PTLD) who have failed rituximab following hematopoietic cell transplant (HCT) or solid organ transplant (SOT).
    - 11 clinical sites for the MATCH and 13 for the ALLELE studies are now open for enrollment in the U.S. with additional sites expected to open in the U.S. and other geographies.

- Presented positive long-term outcomes including durable remissions and encouraging safety findings from two Phase 2 studies of tab-cel™ in EBV+ PTLD at the 23rd Congress of the European Hematology Association (EHA).
    - One- and three-year overall survival (OS) for tab-cel™ treated patients with EBV+ PTLD following HCT who failed rituximab (n=35) was 68% and 55%, respectively. Median OS was not reached after a median of 23.3 months of follow-up in this patient group.
    - In patients with EBV+ PTLD following SOT who failed rituximab, the one- and three-year OS after treatment with tab-cel™ (n=14) was 64% and 43%, respectively. Median survival in this patient group was 21.3 months.
    - None of the EBV+ PTLD patients who had complete or partial responses (CR or PR) after treatment with tab-cel™ died of EBV+ PTLD. Two-year OS for these responding patients was 83% and 86% following HCT (n=24) and SOT (n=7), respectively.
    - Tab-cel™ was associated with durable objective response rate (CR plus PR) of 69% and 50% in patients with EBV+ PTLD following HCT and SOT, respectively, who have failed rituximab.

- U.S. Food and Drug Administration (FDA) accepted IND to initiate 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) that Atara plans to initiate in the second half of 2018.

- Expect to present updated tab-cel™ results in patients with EBV+ cancers in the second half of 2018.

ATA188 & ATA190 for Multiple Sclerosis (MS)

- Announced publication of new research findings advancing the understanding of Epstein-Barr Virus (EBV) infection in the MS-affected brain.
    - The findings were reported in an article online and published in the July 2018 print issue of *Neurology: Neuroimmunology & Neuroinflammation*, an official journal of the American Academy of Neurology.

- A Phase 1 clinical study to evaluate off-the-shelf, allogeneic ATA188 in patients with progressive MS is also underway across clinical sites in the U.S. and Australia.

- The primary objective of the Phase 1 study is to assess the safety of ATA188 in patients followed for at least one year after the first dose. Key secondary endpoints in the study include measures of clinical improvement such as expanded disability status scale (EDSS) and annualized relapse rate (ARR), as well as MRI imaging.
- The first results from the ongoing ATA188 Phase 1 study in patients with progressive MS are expected in the first half of 2019.
- Plan to initiate a randomized autologous ATA190 study in progressive MS patients in 2019.

Development Pipeline

- Plan to rapidly advance novel gene-edited CAR T development programs from recently expanded T-cell immunotherapy collaboration with Memorial Sloan Kettering Cancer Center (MSK), leveraging our existing off-the-shelf T-cell immunotherapy technology platform, manufacturing expertise and research and development capabilities.
- Expect to start Phase 1 study for ATA621 targeting both JC and BK viruses in 2019.

Corporate

- Commenced operations at Atara T Cell Operations & Manufacturing (ATOM) facility in the second quarter of 2018, with completion to support clinical production expected in 2019.
- Appointed Utpal Koppikar as Chief Financial Officer. Utpal has an accomplished track record in global biotechnology financial operations.
- In June 2018 we exercised our option under a license agreement with QIMR Berghofer to an exclusive, worldwide license to develop and commercialize additional T-cell immunotherapy programs including ATA190, as well as the option to license additional technology.

Second Quarter 2018 Financial Results

- Cash, cash equivalents and short-term investments as of June 30, 2018 totaled $417.0 million, which we believe will enable us to expand our near-term pipeline and accelerate pre-commercial activities as well as fund our previously planned operations to mid-2020. In the second quarter of 2018, we sold approximately 1.0 million shares of common stock pursuant to our “at-the-market” (ATM) facility for net proceeds of $47.6 million, after deducting commissions and other offering expenses.

- We reported net losses of $50.9 million, or $1.15 per share, for the second quarter of 2018, as compared to $27.4 million, or $0.94 per share, for the same period in 2017.

- Research and development expenses were $33.4 million for the second quarter of 2018, as compared to $18.3 million for the same period in 2017. The increase in the second quarter of 2018 was due to costs associated with our 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™ in patients with EBV+ PTLD and the Phase 1 clinical trial of allogeneic ATA188 in patients with MS;
  - higher payroll and related costs from increased headcount, and
  - an increase in allocated facilities and information technology expenses.

- Research and development expenses include $3.4 million and $2.0 million of non-cash stock-based compensation expenses in the second quarters of 2018 and 2017, respectively.

- General and administrative expenses were $19.2 million for the second quarter of 2018, as compared to $9.6 million for the same period in 2017. The increase in the second quarter of 2018 was primarily due to increases in professional services costs and payroll and related costs driven by increased headcount to support the Company’s expanding operations. General and administrative expenses include $4.6 million and $3.7 million of non-cash stock-based compensation expenses in the second quarters of 2018 and 2017, respectively.

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

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 103,203	$ 79,223
Short-term investments	313,812	86,873

Restricted cash - short-term	194	194
Prepaid expenses and other current assets	7,861	5,900
Total current assets	425,070	172,190
Property and equipment, net	66,075	44,129
Restricted cash - long-term	1,200	1,200
Other assets	362	260
Total assets	$ 492,707	$ 217,779
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,545	$ 14,711
Accrued compensation	5,276	5,664
Accrued research and development expenses	6,661	4,006
Other current liabilities	8,752	3,265
Total current liabilities	27,234	27,646
Long-term liabilities	12,974	12,269
Total liabilities	40,208	39,915
Commitments and contingencies		
Stockholders' equity:		
Common stock	5	3
Additional paid-in capital	841,975	474,662
Accumulated other comprehensive loss	(505)	(151)
Accumulated deficit	(388,976)	(296,650)
Total stockholders' equity	452,499	177,864
Total liabilities and stockholders' equity	$ 492,707	$ 217,779

Atara Biotherapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 33,387	$ 18,296	$ 61,847	$ 35,837
General and administrative	19,236	9,613	33,228	18,233
Total operating expenses	52,623	27,909	95,075	54,070
Loss from operations	(52,623)	(27,909)	(95,075)	(54,070)
Interest and other income, net	1,743	481	2,752	990
Loss before provision for income taxes	(50,880)	(27,428)	(92,323)	(53,080)
Provision for income taxes	3	—	3	2
Net loss	$ (50,883)	$ (27,428)	$ (92,326)	$ (53,082)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	19	38	(354)	69
Comprehensive loss	$ (50,864)	$ (27,390)	$ (92,680)	$ (53,013)
Net loss per common share:				
Basic and diluted net loss per common share	$ (1.15)	$ (0.94)	$ (2.20)	$ (1.82)
Weighted-average shares outstanding used to calculate basic and diluted net loss per common share	44,379	29,247	42,001	29,152

About Atara Biotherapeutics, Inc.

Atara Biotherapeutics, Inc. (@Atarabio) is a leading T-cell immunotherapy company developing novel treatments for patients with cancer, autoimmune and viral diseases. The Company's off-the-shelf, allogeneic T-cells are bioengineered from donors with healthy immune function and allow for rapid delivery from inventory to patients without a requirement for pretreatment. Atara's T-cell immunotherapies are designed to precisely recognize and eliminate cancerous or diseased cells without affecting normal, healthy cells. Atara's most advanced T-cell immunotherapy in development, tabelecleucel, or tab-cel™ (formerly known as ATA129), is being developed for the treatment of patients with Epstein-Barr virus (EBV) associated post-transplant lymphoproliferative disorder (EBV+ PTLD) who have failed rituximab, as well as other EBV-associated hematologic and solid tumors, including nasopharyngeal carcinoma (NPC). Tab-cel™ is in Phase 3 clinical development for the treatment of EBV+ PTLD following an allogeneic hematopoietic cell transplant (MATCH study) or solid organ transplant (ALLELE study). Atara is also developing off-the-shelf, allogeneic ATA188 and autologous ATA190 T-cell immunotherapies using a complementary targeted antigen recognition technology for specific EBV antigens believed to be important for the potential treatment of multiple sclerosis (MS). A Phase 1 clinical study of autologous ATA190 in patients with progressive MS is ongoing. Atara is also advancing a Phase 1 clinical study of ATA188 in patients with progressive or relapsing-remitting MS across clinical sites in the United States and Australia. Atara's clinical pipeline also includes ATA520 targeting Wilms Tumor 1 (WT1) and ATA230 directed against cytomegalovirus (CMV).

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: enrollment of patients in the Company's clinical trials; opening additional clinical sites in the United States and other geographies; expected results and completion of its Phase 3 studies of tab-cel™; the timing of the Company's submission of a conditional market authorization for tab-cel™ in the EU; the expected start of a Phase 1/2 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 NPC in 2018; the timing and results of the Company's Phase 1 studies of ATA 188 and autologous ATA190 in patients with progressive MS; the Company's ability to rapidly advance its CAR T development programs; 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 under the heading "Risk Factors" in Atara Biotherapeutics' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 1, 2018, including the documents incorporated by reference therein, and subsequent filings with the SEC. 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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