

Fate Therapeutics Reports Third Quarter 2016 Financial Results

IND Filed for FATE-NK100 Adaptive Natural Killer Cell Immunotherapy in Acute Myeloid Leukemia

Orphan Drug Designations for ProTmune Granted by FDA and EMA

ProTmune™ PROTECT Clinical Protocol Amended to Facilitate Path for Accelerated Registration

SAN DIEGO, Nov. 07, 2016 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (NASDAQ:FATE), a biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders, today reported business highlights and financial results for the third quarter ended September 30, 2016.

"During the quarter, we made substantial progress and intensified our commitment towards accelerating the clinical development of ProTmune and bringing innovative natural killer- and T-cell cancer immunotherapies into the clinic," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We significantly bolstered our ability to pursue accelerated registration for ProTmune by instituting investigator and patient blinding in our randomized, controlled PROTECT study. We advanced FATE-NK100, a first-in-class adaptive NK cell product candidate with multi-faceted anti-tumor activity, to IND filing and we are now preparing for the initiation of clinical investigation in early 2017. Additionally, we joined forces with Memorial Sloan Kettering Cancer Center to pioneer the development of off-the-shelf T-cell immunotherapies using engineered induced pluripotent cell lines, a breakthrough approach that enables the continuous production of clonal T-cell products at the scale necessary to serve significant numbers of patients."

Recent Highlights & Program Updates

- | **IND Filed for Adaptive NK Cell Cancer Immunotherapy.** Fate Therapeutics, in collaboration with the Masonic Cancer Center, University of Minnesota, plans to initiate clinical testing in 2017 of FATE-NK100, a first-in-class adaptive natural killer (NK) cell product candidate, for the treatment of refractory or relapsed acute myeloid leukemia (AML). FATE-NK100 has demonstrated in preclinical studies enhanced anti-tumor activity, improved persistence and increased immune checkpoint resistance as compared to NK cell therapies that are being clinically-administered today. New preclinical data from the program are scheduled to be presented at an oral session at the 58th American Society of Hematology (ASH) Annual Meeting and Exposition in December.
- | **Bolstered Path for Accelerated Registration of ProTmune™ PROTECT Study.** The Company amended its protocol for its randomized, controlled Phase 1/2 PROTECT clinical trial of ProTmune. The amendment blinds both investigators and subjects in the study, substantially enhancing its potential to support accelerated registration. In addition, the study eligibility criteria were expanded to include subjects with additional hematologic malignancies, including myelodysplastic syndromes, and to include cytomegalovirus (CMV)-seronegative subjects. ProTmune is currently being evaluated for the prevention of life-threatening complications, including acute graft-versus-host disease (GvHD), in adult subjects with hematologic malignancies undergoing allogeneic mobilized peripheral blood hematopoietic cell transplantation (HCT).
- | **Granted Broad Orphan Drug Designations by FDA and EMA for ProTmune.** In September, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation and, in October, the European Medicines Agency (EMA) granted Orphan Medicinal Product Designation, for ProTmune. The designation granted by each agency broadly covers subjects undergoing allogeneic HCT across diseases for which the procedure is performed, including blood cancers and genetic disorders. In June 2016, the FDA granted Fast Track designation for ProTmune for the reduction of incidence and severity of acute GvHD in patients undergoing allogeneic HCT.
- | **Launched Off-the-Shelf T-Cell Immunotherapy Partnership with Memorial Sloan Kettering.** The multi-year collaboration led by Michel Sadelain, M.D., Ph.D., Director of the Center for Cell Engineering and the Stephen and Barbara Friedman Chair at Memorial Sloan Kettering Cancer Center (MSK), is advancing T-cell product candidates derived from engineered induced pluripotent cells. Like master cell lines used for the manufacture of monoclonal antibodies, pluripotent cell lines can serve as a renewable cell source for the consistent manufacture of clonal populations of effector cells for off-the-shelf treatment of patients. In connection with the partnership, Fate Therapeutics also exclusively licensed from MSK foundational intellectual property covering T cells and NK cells derived from induced pluripotent cells engineered with chimeric antigen receptors.
- | **Completed \$10.3M Common Stock Private Placement.** In August, Fate Therapeutics issued 5.25 million shares of common stock at \$1.96 per share pursuant to a securities purchase agreement with certain institutional investors

including Franklin Advisers, Inc.

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- | **Cash & Short-term Investment Position:** Cash, cash equivalents and short-term investments as of September 30, 2016 were \$46.6 million compared to \$64.8 million as of December 31, 2015. The decrease was primarily driven by the Company's use of cash to fund operating activities and to service principal and interest obligations under its loan agreement with Silicon Valley Bank. This use was partially offset by \$10.2 million in net proceeds received by the Company in August 2016 in connection with its private placement of common stock to certain institutional investors.
- | **Total Revenue:** Revenue was \$1.0 million for the third quarter of 2016 as well as for the comparable period in 2015. All revenue was derived from the Company's research collaboration and license agreement with Juno Therapeutics.
- | **Total Operating Expenses:** Total operating expenses were \$9.4 million for the third quarter of 2016 compared to \$7.4 million for the comparable period in 2015. Operating expenses for the third quarter of 2016 included \$0.8 million of stock compensation expense, compared to \$0.6 million for the comparable period in 2015.
- | **R&D Expenses:** Research and development expenses were \$6.8 million for the third quarter of 2016 compared to \$5.0 million for the comparable period in 2015. The increase in R&D expenses was primarily related to an increase in third-party service provider fees to support the Company's clinical development of ProTmune and preclinical development of FATE-NK100 in collaboration with the University of Minnesota, and an increase in personnel expenses resulting from the hiring of additional employees to support the conduct of its research activities, including activities under its collaboration with Juno.
- | **G&A Expenses:** General and administrative expenses were \$2.6 million for the third quarter of 2016 compared to \$2.4 million for the comparable period in 2015. The increase in G&A expenses was primarily related to an increase in intellectual property-related expenses.
- | **Common Shares Outstanding:** Common shares outstanding as of September 30, 2016 were 34.1 million compared to 28.7 million as of December 31, 2015. Common shares outstanding increased primarily as a result of the Company's issuance of 5.25 million shares of common stock in August 2016 in connection with its private placement of common stock to certain institutional investors.

Today's Conference Call and Webcast

The Company will conduct a conference call today, Monday, November 7, 2016 at 5:00 p.m. ET to review financial and operating results for the quarter ended September 30, 2016. In order to participate in the conference call, please dial 1-877-303-6235 (domestic) or 1-631-291-4837 (international) and refer to conference ID 6469174. The live webcast can be accessed under "Events & Presentations" in the Investors & Media section of the Company's website at www.fatetherapeutics.com. The archived webcast will be available on the Company's website beginning approximately two hours after the event.

About ProTmune™

ProTmune™ is an investigational programmed cellular immunotherapy undergoing clinical development for the prevention of life-threatening complications, including acute graft-versus-host disease, in patients undergoing allogeneic hematopoietic cell transplantation. ProTmune is manufactured by modulating a donor-sourced, mobilized peripheral blood graft *ex vivo* with two small molecules (FT1050 and FT4145) to enhance the biological properties and therapeutic function of the graft's cells. The programmed mobilized peripheral blood graft is administered to a patient as a one-time intravenous infusion. ProTmune has been granted Orphan Drug and Fast Track Designations by the U.S. Food and Drug Administration, and Orphan Medicinal Product Designation by the European Medicines Agency.

About Fate Therapeutics, Inc.

Fate Therapeutics is a biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's hematopoietic cell therapy pipeline is comprised of NK- and T-cell immuno-oncology programs, including off-the-shelf product candidates derived from engineered induced pluripotent cells, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation and to promote immune tolerance in patients with autoimmune disease. Its adoptive cell therapy programs are based on the Company's novel *ex vivo* cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the Company's advancement of and plans related to the Company's product candidates, clinical studies, research and development programs, and partnerships, the Company's progress and plans for

its clinical investigation of ProTmune™ and of FATE-NK100, the Company's expected product registration strategy for ProTmune, including its ability to pursue accelerated registration, the ability of ProTmune to prevent, or reduce the incidence or severity of life-threatening complications, including acute graft-versus-host disease and severe viral infections including CMV infection, and the Company's projected cash expenditures. These and any other forward-looking statements in this release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that results observed in prior studies, including preclinical studies of ProTmune and the Company's other product candidates, will not be observed in ongoing or future studies involving these product candidates, the risk that the Company may cease or delay preclinical or clinical development activities for any of its existing or future product candidates for a variety of reasons (including requirements that may be imposed by regulatory authorities and requirements for regulatory approval, difficulties or delays in patient enrollment in current and planned clinical trials, and any adverse events or other negative results that may be observed during preclinical or clinical development), the risk that the Company's research collaborations may not be successful or may be terminated, and the risk that the Company's expenditures may exceed current expectations for a variety of reasons. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in the Company's periodic filings with the Securities and Exchange Commission, including but not limited to the Company's most recently filed periodic report, and from time to time the Company's other investor communications. Fate Therapeutics is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

Availability of Other Information about Fate Therapeutics, Inc.

Investors and others should note that the Company routinely communicates with investors and the public using its website (www.fatetherapeutics.com) and its investor relations website (ir.fatetherapeutics.com), including without limitation, through the posting of investor presentations, SEC filings, press releases, public conference calls and webcasts on these websites. The information posted on these websites could be deemed to be material information. As a result, investors, the media, and others interested in Fate Therapeutics are encouraged to review this information on a regular basis. The contents of the Company's website, or any other website that may be accessed from the Company's website, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
		(unaudited)		
Collaboration revenue	\$ 1,026	\$ 1,026	\$ 3,375	\$ 1,355
Operating expenses:				
Research and development	6,804	5,003	20,222	14,428
General and administrative	2,611	2,351	7,462	7,797
Total operating expenses	9,415	7,354	27,684	22,225
Loss from operations	(8,389)	(6,328)	(24,309)	(20,870)
Other income (expense):				
Interest income	37	4	95	7
Interest expense	(385)	(562)	(1,308)	(1,683)
Total other expense, net	(348)	(558)	(1,213)	(1,676)
Net loss	\$ (8,737)	\$ (6,886)	\$ (25,522)	\$ (22,546)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	(8)	—	3	—
Comprehensive loss	\$ (8,745)	\$ (6,886)	\$ (25,519)	\$ (22,546)
Net loss per common share, basic and diluted	\$ (0.27)	\$ (0.24)	\$ (0.85)	\$ (0.92)
Weighted-average common shares used to compute basic and diluted net loss per share	32,090,174	28,650,356	29,920,075	24,404,740

Condensed Consolidated Balance Sheets (in thousands)

	September 30, 2016	December 31, 2015
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 37,099	\$ 64,809
Short-term investments	9,520	—
Prepaid expenses and other current assets	780	843
Total current assets	<u>47,399</u>	<u>65,652</u>
Long-term assets	1,896	2,306
Total assets	<u><u>\$ 49,295</u></u>	<u><u>\$ 67,958</u></u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,543	\$ 3,435
Long-term debt, current portion	8,025	7,550
Current portion of deferred revenue	2,105	2,401
Other current liabilities	5	55
Total current liabilities	<u>14,678</u>	<u>13,441</u>
Long-term debt, net of current portion	4,610	10,688
Deferred revenue	3,355	4,934
Other long-term liabilities	1,279	857
Stockholders' equity	25,373	38,038
Total liabilities and stockholders' equity	<u><u>\$ 49,295</u></u>	<u><u>\$ 67,958</u></u>

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