

December 7, 2015

## **Fate Therapeutics Provides Update on Adoptive Immunotherapy Programs for Hematopoietic Cell Transplantation**

*Supportive Interim Data from ProHema® PUMA Study Demonstrate the Therapeutic Potential of Programmed Donor Cells*

*Clinical Development Strategy to Focus on Prevention of Life-Threatening Complications in Mobilized Peripheral Blood HCT*

*ProTmune™ to Advance into Phase 1/2 Clinical Trial for Prevention of Acute Graft-versus-Host Disease & Severe Viral Infections*

*ProHema Clinical Development to be Discontinued in Cord Blood HCT*

SAN DIEGO, Dec. 7, 2015 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (NASDAQ:FATE), a biopharmaceutical company dedicated to the development of programmed cellular immunotherapeutics for the treatment of cancer and immune disorders, announced today supportive data from the Company's Phase 2 PUMA clinical trial of ProHema and provided an update on its therapeutic strategy for hematopoietic cell transplantation (HCT). The Company expects to initiate an open-label, randomized, controlled Phase 1/2 clinical trial of ProTmune in 2016 to investigate the potential of ProTmune to prevent acute graft-versus-host disease (GvHD) and severe viral infections in patients undergoing mobilized peripheral blood HCT. With the benefit of ProTmune advancing into the clinic, the Company will discontinue further development of ProHema in patients undergoing cord blood HCT.

"We are pleased that the PUMA data continue to support our initial aim of improving neutrophil engraftment in cord blood HCT and, more importantly, our growing therapeutic focus on programming immune cells," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "With the increasing utilization of mobilized peripheral blood HCT, we believe the development of ProTmune, which is specifically intended to prevent T cell-mediated complications including acute GvHD in mobilized peripheral blood HCT, offers a more compelling therapeutic and pharmacoeconomic value proposition compared to ProHema. Programming donor immune cells just prior to administration to a patient undergoing HCT is a paradigm-changing approach and has the potential to significantly improve patient outcomes, mitigate the use of toxic and immune-suppressive drugs following HCT, and reduce the overall cost of care."

### ***PUMA Study Results***

The open-label, randomized, controlled PUMA study was designed to assess ProHema in adult subjects undergoing cord blood HCT. Based on an October 15th data cut-off, an interim analysis of the PUMA study showed that subjects administered ProHema had an increase in the incidence of early neutrophil engraftment and a reduction in the incidence of severe viral infection-related adverse events (Grade 3-5) following HCT. Specifically, the analysis showed:

- | 24 of 28 subjects administered ProHema achieved neutrophil engraftment. 16 of these 24 subjects (67%) achieved early neutrophil engraftment prior to a pre-specified historical control median time of engraftment (which has been established as Day 26 for subjects receiving myeloablative conditioning and Day 21 for subjects receiving reduced intensity conditioning). The overall reduction in the median time to neutrophil engraftment was 4.5 days, as compared to the applicable pre-specified historical control value.
- | 14 of 15 concurrent control subjects achieved neutrophil engraftment. Eight of these 14 subjects (57%) achieved early neutrophil engraftment prior to the applicable pre-specified historical control median. The overall reduction in the median time to neutrophil engraftment was 2 days, as compared to the applicable pre-specified historical control value.
- | 32% of subjects administered ProHema (9 of 28), as compared to 60% of concurrent control subjects (9 of 15), experienced one or more severe viral infection-related adverse events (Grade 3-5) following HCT; and, of the subjects who were cytomegalovirus (CMV)-seropositive at the time of HCT, 11% of subjects administered ProHema (2 of 18), as compared to 30% of concurrent control subjects (3 of 10), experienced one or more severe CMV-related adverse events (Grade 3-5) following HCT.

### ***ProTmune Advancing to the Clinic***

Fate Therapeutics is developing ProTmune, an adoptive immunotherapeutic programmed with two small molecules, to prevent acute GvHD while maintaining the cancer-fighting properties of donor mobilized peripheral blood (mPB) T cells. New preclinical data for ProTmune presented at the American Society of Hematology 2015 Annual Meeting show that a single administration of programmed mPB cells results in a statistically-significant reduction in GvHD score and improvement in survival as compared to

vehicle-treated cells. Importantly, the Company has also shown that the cancer-fighting properties of adoptively transferred programmed T cells are preserved in preclinical models.

mPB is the predominant and a growing source of hematopoietic cells utilized in allogeneic HCT procedures. According to the Center for International Blood and Marrow Transplant Research, there are approximately 30,000 allogeneic HCT procedures performed globally each year, of which approximately 65% use mobilized peripheral blood, 24% use bone marrow and 11% use cord blood.

While mPB offers a cost-effective and convenient cell source that promotes rapid and reliable neutrophil engraftment, T cell-mediated complications following mPB HCT, such as GvHD, are a significant cause of morbidity and mortality. The incidence of acute GvHD at Day 100 post-HCT is in the range of 34-40% for matched related donors and 47-52% for matched unrelated donors, and disease relapse, GvHD and infections are the primary causes of death following allogeneic HCT. There are currently no approved therapies for the prevention of GvHD in patients undergoing allogeneic HCT, giving rise to a significant unmet medical need for therapies that can prevent GvHD while preserving the cancer-fighting properties of the adoptively transferred donor T cells.

Mr. Wolchko continued, "During 2015, we established new strategic and therapeutic opportunities for value-creation based on our programming of immune cells. Our development of ProTmune exemplifies our commitment to advancing programmed cellular immunotherapeutics with profound therapeutic potential addressing significant unmet medical needs. Additionally, we entered into three strategic collaborations, all of which are aimed at developing novel cell-based immunotherapeutics for cancer and immune disorders. Finally, we focused our proprietary pluripotent cell platform, which enables the generation of genetically-modified, clonal pluripotent cell lines, to serve as a continual source for immune cell derivation, and we are poised to demonstrate in 2016 its disruptive potential for off-the-shelf production of engineered T-cell and NK-cell cancer immunotherapeutics without requiring patient-sourced cells."

### **Investor Conference Call and Webcast Information**

The Company will host a conference call and webcast at 8:00 a.m. ET today, December 7, 2015, to discuss the ProHema PUMA study and provide a corporate update. 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 93993476. The live webcast can be accessed under "Events & Presentations" in the Investors & Media section of the Company's website at [www.fatetherapeutics.com](http://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 produced by modulating mobilized peripheral blood (mPB) *ex vivo* with two small molecules to enhance the immune tolerance and anti-infective activity of donor cells. The programmed mPB cells are then adoptively transferred to a patient undergoing allogeneic HCT through a single administration. New preclinical data for ProTmune were presented at the American Society of Hematology 2015 Annual Meeting, demonstrating that programmed CD4+ and CD8+ T cells of mPB are functionally less allo-reactive. Notably, these data indicate a decrease in both the expression of costimulatory receptors and the production of pro-inflammatory cytokines, and an increase in the production of anti-inflammatory cytokines such as IL-10. Additionally, a single administration of the programmed mPB cells showed a statistically-significant reduction in GvHD score and improvement in survival, as compared to vehicle-treated cells, in preclinical models. Importantly, the Company has also shown that the cancer-fighting properties of adoptively transferred programmed T cells are preserved in preclinical models.

### **About Fate Therapeutics, Inc.**

Fate Therapeutics is a biopharmaceutical company dedicated to the development of programmed cellular immunotherapeutics for the treatment of cancer and immune disorders. The Company's cell-based product pipeline is comprised of off-the-shelf immuno-oncology therapeutics, including NK- and T-cell-based candidates derived from induced pluripotent cells, and immuno-regulatory therapeutics, including hematopoietic cell-based candidates for protecting the immune system of patients undergoing hematopoietic cell transplantation and for suppressing auto-reactive T cells of patients with auto-immune disorders. Its adoptive cell therapy candidates 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](http://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 therapeutic and market potential of programmed cellular immunotherapeutics, including ProTmune, the Company's intention to initiate a clinical trial for ProTmune during 2016, the potential ability of ProTmune to reduce the incidence of acute GvHD and severe viral infections, the Company's plans and ability to develop programmed cellular immunotherapeutics, including ProTmune, and the Company's ability to develop off-the-shelf cellular immunotherapies from its pluripotent cell platform. 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 of cessation or delay of planned development and clinical activities for a variety of reasons (including any adverse events or other results that may be observed during development), any inability to develop programmed cellular immunotherapeutics which are suitable for therapeutic applications, the risk that results observed in prior preclinical studies of ProTmune may not be replicated in subsequent studies or clinical trials, the risk that ProTmune or programmed cellular immunotherapeutics that the Company may develop may not produce therapeutic benefits or may cause other unanticipated adverse effects, and the risk that the Company may allocate its financial and other resources to programs or product candidates that ultimately have less therapeutic or commercial potential than other product opportunities. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's 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 Form 10-Q for the quarter ended September 30, 2015, and from time to time the Company's other investor communications. The Company 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.

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