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Fate Therapeutics Announces Interim Data From Ongoing Phase 2 PUMA Study

Key Metrics of Neutrophil Engraftment Improved in PROHEMA Arm

Independent Data Monitoring Committee Supports Continuation of Study Enrollment

Full Results on Primary Efficacy Endpoint Expected in mid-2015

SAN DIEGO, Dec. 18, 2014 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (Nasdaq:FATE), a biopharmaceutical company engaged in the discovery and development of adult stem cell modulators to treat orphan diseases, today reported initial data from the first 12 subjects administered PROHEMA® in the Company's ongoing Phase 2 PUMA study and announced that the study's independent Data Monitoring Committee (iDMC) supported continuation of the clinical trial following a second planned interim safety review. These early data showed that subjects administered PROHEMA, the Company's lead *ex vivo* programmed hematopoietic cellular therapeutic derived from umbilical cord blood, had an improved median time of neutrophil engraftment and an increased incidence of early neutrophil engraftment.

"Our evaluation of these initial data from 12 subjects shows that small molecule-based programming of hematopoietic stem cells and T cells *ex vivo* can positively affect the biological activity of these cells *in vivo.* Given that many of the complications contributing to the 25-30% early mortality following allogeneic hematopoietic stem cell transplantation are tied to the function of donor-derived HSCs and T cells, we believe our *ex vivo* programming paradigm can meaningfully improve outcomes of this potentially curative procedure," said Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of Fate Therapeutics. "In 2015, we expect to report on multiple clinical milestones in our PROHEMA development program, including full results on the primary and secondary endpoints of this PUMA study, as well as clinical data read-outs from our PROMPT and PROVIDE studies in pediatric patients with hematologic malignancies and inherited metabolic disorders, respectively."

PROHEMA is derived by programming the biological properties of allogeneic hematopoietic cells *ex vivo* using a small molecule pharmacologic modulator, optimizing their *in vivo* therapeutic potential. Of the first 12 subjects administered PROHEMA in the Phase 2 PUMA study, 10 subjects received myeloablative conditioning (MAC) and two subjects received reduced-intensity conditioning (RIC). Eight of 10 PROHEMA subjects receiving MAC achieved neutrophil engraftment, with a median time of engraftment of 20 days. One of two PROHEMA subjects receiving RIC achieved neutrophil engraftment, which was reached on Day 14. Historical median times of neutrophil engraftment are approximately 26 days for patients receiving MAC and 21 days for patients receiving RIC based on multi-center reports published in the literature of adult patients undergoing double umbilical cord blood transplantation in the United States. Six of the nine engrafting subjects administered PROHEMA in the PUMA study achieved neutrophil engraftment prior to these historical median times.

The engraftment of donor-derived hematopoietic stem cells (HSCs) in patients undergoing hematopoietic stem cell transplantation (HSCT) is essential for the successful reconstitution of a new blood and immune system. Complications from delayed or failed neutrophil engraftment following allogeneic HSCT are a leading contributor to non-relapse mortality, and this risk increases by 2.5-fold in patients with delayed neutrophil recovery. The PUMA study is designed to evaluate the effect of PROHEMA on hematopoietic reconstitution and immune-mediated outcomes across multiple clinical endpoints that contribute significantly to the overall morbidity and mortality of allogeneic HSCT. These include time to and incidence of neutrophil and platelet engraftment, engraftment failure, bacterial infections, viral reactivation, graft versus host disease, relapse of underlying disease and overall and disease-free survival.

On December 16, 2014, the PUMA study's iDMC conducted its second of two scheduled interim safety reviews of PROHEMA. A total of 20 subjects, including 12 subjects that received PROHEMA plus an unmanipulated cord blood unit and eight control subjects that received two unmanipulated cord blood units, were included in the interim review, which assessed safety, time to engraftment, rates of graft failure, early mortality, infection and graft versus host disease. Two early deaths prior to engraftment, which were both attributed to the toxicity of the conditioning regimen received by the subjects, were reported in the PROHEMA arm, and one subject administered PROHEMA failed to achieve neutrophil engraftment. Based on its consideration of the data available on the first 20 subjects as well as historical outcomes reported from multi-center clinical experiences, the iDMC determined that PROHEMA had met established safety criteria and supported continuation of the PUMA study. The Company believes that data from its Phase 2 control subjects are consistent with expected outcomes of patients undergoing double umbilical cord blood transplantation published in the literature, including historical median times of neutrophil engraftment.

"There are an estimated 15,000 patients in need of a donor-derived transplant each year, and up to 40 percent of these patients do not have access to a matched donor source. Given its rapid accessibility and less stringent HLA matching

requirements, as well as the significantly lower rates of relapse reported following its clinical use, umbilical cord blood is an advantageous source of hematopoietic cells for allogeneic transplantation," said Pratik Multani, M.D., Chief Medical Officer of Fate Therapeutics. "Initial data on neutrophil engraftment from the PUMA study provide encouragement that PROHEMA may address delayed hematopoietic reconstitution, which is the most significant barrier to umbilical cord blood's broad clinical use as a potentially curative treatment for patients with hematologic malignancies and severe inherited blood and immune disorders."

In addition to its conduct of the PUMA study, Fate Therapeutics is currently investigating the therapeutic potential of PROHEMA in a Phase 1b clinical trial in pediatric patients with hematologic malignancies (PROMPT), and plans to initiate a Phase 1b clinical trial of PROHEMA in pediatric patients with inherited metabolic disorders (PROVIDE).

About PROHEMA®

PROHEMA® is an *ex vivo* programmed hematopoietic cellular therapeutic derived from umbilical cord blood. PROHEMA is produced through a proprietary, two-hour programming process, where the biological properties of hematopoietic stem cells (HSCs) and T cells of umbilical cord blood are modulated *ex vivo* using a small molecule pharmacologic modulator to optimize these cells' therapeutic potential *in vivo*. The programming process, which uses the small molecule pharmacologic modulator FT1050 (16,16 dimethyl prostaglandin E_2, or dmPGE_2), induces rapid activation of genes involved in the homing, proliferation and survival of HSCs and the cell cycle, immune tolerance and anti-viral properties of T cells. PROHEMA is currently being developed as a donor source of hematopoietic cells for use in allogeneic HSCT for the treatment of a wide range of hematologic malignancies in adult and pediatric patients and for the treatment of a wide range of inherited metabolic disorders in pediatric patients. In 2010, the FDA granted PROHEMA orphan designation for the enhancement of HSC engraftment in patients undergoing umbilical cord blood transplantation.

About the Phase 2 PUMA Study

The PUMA (PROHEMA® in UMbilical cord blood transplant in Adults) study is a randomized, controlled, open-label Phase 2 clinical trial of PROHEMA in adult subjects undergoing double umbilical cord blood transplantation for the treatment of hematologic malignancies including acute lymphoblastic leukemia (ALL), acute myelogenous leukemia (AML) and non-Hodgkin lymphoma (NHL). Multiple clinical endpoints that contribute significantly to the overall morbidity and mortality of allogeneic HSCT are being investigated in the PUMA study to inform and support potential registrational strategies. These clinical endpoints include key measures of the hematopoietic reconstitution and immunotherapeutic potential of PROHEMA including time to and incidence of neutrophil and platelet engraftment, engraftment failure, bacterial infections, viral reactivation, graft versus host disease, relapse of underlying disease and overall and disease-free survival.

The Phase 2 PUMA study is designed to enroll 60 subjects. Eligible subjects are randomized, at a ratio of 2:1, with approximately 40 subjects intended to receive PROHEMA plus an unmanipulated cord blood unit, and approximately 20 subjects intended to receive two unmanipulated cord blood units. Based upon physician choice, subjects are treated with one of two conditioning regimens, an intense myeloablative regimen or a reduced-intensity regimen, to destroy malignant cells and to prevent rejection of the donor hematopoietic cells. Randomization will be stratified by conditioning regimen. An independent Data Monitoring Committee is providing safety oversight during the conduct of the PUMA study.

The primary endpoint of the 60-subject Phase 2 PUMA study is based on a categorical analysis of neutrophil engraftment, and the clinical trial is powered to show with statistical significance that 70% of subjects with neutrophil engraftment in the PROHEMA treatment arm engraft prior to a pre-specified control day of neutrophil engraftment. The pre-specified control day of neutrophil engraftment, which is dependent on the conditioning regimen received by the subject, has been established as 26 days for subjects receiving myeloablative conditioning and 21 days for subjects receiving reduced-intensity conditioning. These pre-specified values are based on multi-center reports published in the literature of historical median times to neutrophil engraftment in adult patients undergoing double umbilical cord blood transplantation in the United States (Brunstein, *Blood*. 2010;116(22): 4693-4699; Cutler, *Bone Marrow Transplantation*. 2011;46(5): 659-67). The Phase 2 PUMA study utilizes the concurrent control arm to validate the pre-specified values of neutrophil engraftment and to provide context for interpretation of other clinical outcomes. Full data on the primary efficacy endpoint from the Phase 2 PUMA study are expected in mid-2015.

About Hematopoietic Stem Cell Transplantation

Allogeneic hematopoietic stem cell transplantation (HSCT) is an established procedure performed with curative intent in patients with a wide range of hematologic malignancies and life-threatening inherited immune and blood disorders. More than 20,000 allogeneic HSCTs are performed annually worldwide to achieve long-term disease-free remission and/or functional cures. The majority of HSCTs are performed in adults for the treatment of hematologic malignancies and in children for the treatment of inherited disorders. Disease-free survival rates of approximately 40-50% at two- and five-years following HSCT have been reported in multi-center clinical experiences for the treatment of hematologic malignancies.

The procedure involves transferring donor-derived hematopoietic cells, including stem cells and T cells, from mobilized

peripheral blood, bone marrow or umbilical cord blood to a patient following the administration of chemotherapy and/or radiation therapy. Donor-derived hematopoietic stem cells (HSCs) and T cells each play an essential role in allogeneic HSCT - donor HSCs traffic to and engraft in the bone marrow, replacing the patient's blood and immune system, and T cells traffic to and engage cancer cells, acting as an immunotherapeutic to eliminate residual malignancy. Delay or failure of HSC engraftment leaves a patient severely immuno-compromised and exposes the patient to significant risk of early mortality. Additionally, while the donor T cells impart a critical immunotherapeutic effect, the reactivity of donor T cells can result in a serious complication known as graft versus host disease, where donor T cells recognize antigens on patient's cells as foreign and attack the patient's cells. While allogeneic HSCT holds curative potential, the majority of relapse and non-relapse mortality occurs within the initial months of the procedure, where the rate of relapse and non-relapse mortality is approximately 25-30% at Day 100 following HSCT.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company engaged in the discovery and development of pharmacologic modulators of adult stem cells to treat severe, life-threatening diseases. The Company's approach utilizes established pharmacologic modalities, such as small molecules, and targets well-characterized biological mechanisms to program the fate and enhance the therapeutic potential of adult stem cells. The Company's lead product candidate, PROHEMA®, is an *ex vivo* programmed hematopoietic cellular therapeutic, which is currently in clinical development for patients undergoing HSCT. The Company is also applying its reprogramming modulators to develop human induced pluripotent stem cell-derived cellular therapeutics, and evaluating the *in vivo* programming of muscle satellite stem cells using its Wnt7a-based protein analogs for muscle regeneration. 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 potential safety and efficacy of PROHEMA® (including statements relating to observations of improved median times to engraftment and increased incidence of early engraftment in subjects treated with PROHEMA in the PUMA study), the Company's clinical development plans for PROHEMA and the availability of clinical data and results. 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. In particular, the PUMA study is currently ongoing and in the earlier stages of patient enrollment and evaluation, there is limited data concerning treatment with PROHEMA in the PUMA study, and the announced data are preliminary in nature. Additional risks and uncertainties include, but are not limited to, the risks that the results of PROHEMA observed in prior preclinical and clinical development, and in these preliminary data in the PUMA study, may not be replicated in ongoing or future clinical trials of PROHEMA, the risk that any conclusions drawn from preliminary data on a subset of patients may not be supported based on subsequent data, and the risk of cessation or delay of any clinical development activities for a variety of reasons (including additional information that may be requested or additional obligations that may be imposed by the FDA, any difficulties or delays in patient enrollment in current and planned clinical trials, and any adverse events or other negative results that may be observed in these trials). 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 Form 10-Q for the quarter ended September 30th, 2014, 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.

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