March 12, 2014

Fate Therapeutics Commences Phase 2 Clinical Trial of PROHEMA(R) for the Treatment of Hematologic Malignancies

First Patient Enrolled in PUMA Study

Approved for Conduct at Ten Leading U.S. Centers

Interim Data Expected in 2H14

SAN DIEGO, March 12, 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, announced today the enrollment of the first patient in its "PUMA" (PROHEMA® in UMbilical cord blood transplant in Adults) study, a Phase 2 clinical trial of PROHEMA® (16, 16-dimethyl prostaglandin E2, or dmPGE2, modulated cord blood) using the Company's nutrient-rich media formulation. The PUMA study is designed to assess the efficacy and safety of PROHEMA® in a randomized, controlled setting in patients undergoing hematopoietic stem cell (HSC) transplantation for the treatment of hematologic malignancies. The trial has been approved for conduct at ten major HSC transplant centers in the United States. Safety reviews are planned after six and 12 subjects, respectively, have been treated with PROHEMA® in the PUMA study, and the Company intends to provide a clinical update following the completion of these reviews. Full data on the primary efficacy endpoint are expected in mid-2015.

"Despite important advancements in the pharmacotherapy of blood cancers, many patients with leukemia or lymphoma advance to a stage where hematopoietic stem cell transplantation represents the only curative therapeutic option," commented Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of Fate Therapeutics. "PROHEMA® is representative of Fate's commitment to developing stem cell therapeutics to address significant unmet medical needs and offer life-saving therapeutic solutions to patients with hematologic malignancies and rare genetic disorders. We have worked diligently to optimize the clinical potency and efficacy profile of PROHEMA®, and we are excited to pursue clinical development of PROHEMA® in both malignant and non-malignant disorders."

During 2013, scientists at Fate Therapeutics demonstrated that the therapeutic profile of PROHEMA® may be further enhanced, as compared to its previous clinical use, by incorporating the Company's nutrient-rich media (NRM) formulation into the manufacture of PROHEMA®. In *in vivo* preclinical studies, PROHEMA® manufactured using its NRM formulation exhibited improved HSC viability and a more than two-fold improvement in HSC engraftment as compared to a standard cell processing media used previously in the clinical development of PROHEMA®. The Company has worked closely with the FDA over the past nine months to enable the clinical manufacture of PROHEMA® using its NRM formulation for the PUMA study.

"While allogeneic HSC transplantation is a proven therapeutic intervention with curative potential for patients with hematologic malignancies and over 50 rare genetic disorders, it is associated with significant treatment-related limitations and 100-day mortality rates between 20% to 30%," said Corey Cutler M.D., M.P.H., F.R.C.P.C., Associate Professor of Medicine at the Dana-Farber Cancer Institute and Harvard Medical School and principal investigator in the PUMA trial and the Company's prior clinical trials of PROHEMA®. "Engraftment, particularly as measured by time to the engraftment of neutrophils, is correlated with key clinical outcomes of HSC transplantation including the length of hospital stays, rates of serious infections and overall treatment-related morbidity and mortality. I applaud Fate Therapeutics for its dedication and effort in bringing the most optimal product candidate to patients."

The PUMA study is an open-label, randomized, controlled, multi-center Phase 2 clinical trial designed to enroll 60 subjects, age 15 to 65 years, and will use the Company's NRM formulation in the manufacture of PROHEMA®. Patients will be randomized at a ratio of 2:1, with approximately 40 patients receiving PROHEMA® plus an unmanipulated cord blood unit and approximately 20 patients receiving two unmanipulated cord blood units. At the discretion of the treating physician, patients will be conditioned using an intensive myeloablative or a reduced intensity regimen. The primary endpoint of the PUMA study is the cumulative incidence of time to neutrophil engraftment as compared to a pre-specified control median, which will be adjusted based upon the median time to neutrophil engraftment calculated for the patients enrolled in the control arm. Secondary endpoints include additional measures of neutrophil and platelet engraftment, rates of graft failure, acute graft versus host disease and serious infection, and disease-free and overall survival.

About PROHEMA®

PROHEMA® is a pharmacologically-modulated, cord blood-derived hematopoietic stem cell (HSC) therapeutic. PROHEMA® is produced through a proprietary, two-hour, *ex vivo* cell modulation process that results in rapid activation of key biological pathways involved in homing, proliferation and survival of HSCs. In preclinical testing, PROHEMA® has demonstrated the potential to accelerate engraftment and to drive durable hematopoietic reconstitution, without the need for multi-week expansion protocols. In an initial Phase 1b clinical trial in adult patients with hematologic malignancies undergoing double umbilical cord blood transplant (dUCBT), the median time to neutrophil recovery (> 500 cells/µL) with PROHEMA® was 17.5 days, which compares favorably to historical norms for patients undergoing dUCBT. In that trial, 100-day survival with PROHEMA® was 100%, and PROHEMA® provided the dominant source of hematopoiesis in 10 of 12 evaluable subjects, suggesting that treatment with PROHEMA® may accelerate engraftment and drive durable and preferential hematologic reconstitution.

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 orphan diseases, including certain hematologic malignancies, lysosomal storage disorders and muscular dystrophies. The Company utilizes established pharmacologic modalities, including small molecules and therapeutic proteins, and well-characterized biological mechanisms to enhance the therapeutic potential of adult stem cells. The Company has built two adult stem cell modulation platforms: a hematopoietic stem cell (HSC) modulation platform, which seeks to optimize the therapeutic potential of HSCs for treating patients with hematologic malignancies and rare genetic disorders that are undergoing hematopoietic stem cell transplantation, and a muscle satellite stem cell modulation platform, which seeks to activate the regenerative capacity of muscle for treating patients with degenerative muscle disorders. The Company is presently advancing its lead product candidate, PROHEMA®, a pharmacologically-modulated HSC therapeutic derived from umbilical cord blood, in Phase 2 clinical development for hematologic malignancies. Fate Therapeutics is also advancing its proprietary Wnt7a protein analogs in preclinical development for the treatment of muscular dystrophies. 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 therapeutic potential of PROHEMA®, and our clinical development plans for PROHEMA®, including the timing of, and our ability to conduct, safety reviews of subjects in the PUMA study, and the timing and availability of both interim and full data in the trial. 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 any ongoing or planned preclinical or 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 as a condition to our continuation of clinical trials with PROHEMA®, any difficulties or delays in patient enrollment in the PUMA study, and any adverse events or other negative results that may be observed in the PUMA study. 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 30, 2013, and from time to time the company's other investor communications. Fate Therapeutics is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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