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Fate Therapeutics Highlights Effects of Nutrient-Rich Media on Ex Vivo Programmed CD34+ Cells Sourced From Umbilical Cord Blood

SAN DIEGO, Dec. 8, 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, will present today an overview of the effects of using its nutrient-rich media (NRM) formulation in the *ex vivo* programming of CD34+ cells sourced from umbilical cord blood. Scientists from Fate Therapeutics have shown that, using the Company's NRM formulation as compared to a standard cell processing media commonly used in clinical practice, CD34+ cells programmed with FT1050 (16,16 dimethyl prostaglandin E_2 , or $dmPGE_2$) had an 8-fold increase in CXCR4 gene expression and significantly increased cell-surface protein expression of CXCR4, a key receptor implicated in the homing of hematopoietic stem cells (HSCs) to the bone marrow niche. Additionally, *ex vivo* programmed CD34+ cells exhibited a more than two-fold improvement in HSC engraftment in a xeno-transplantation study in NSG mice at 12-weeks post-transplant. These findings will be presented today at the 56th Annual Meeting and Exposition of the American Society of Hematology (ASH) in San Francisco, California during a poster presentation entitled "*Ex Vivo* Pharmacologic Modulation in a Nutrient-Rich Medium to Accelerate Engraftment of Human Umbilical Cord Blood."

The Company's lead product candidate, PROHEMA®, is an *ex vivo* programmed hematopoietic cellular therapeutic that utilizes FT1050 and the NRM formulation in its manufacture. During the fourth quarter of 2014, Fate Therapeutics expects an independent Data Monitoring Committee (iDMC) to conduct a second data review of the Company's PUMA study, a 60-patient randomized, controlled, open-label Phase 2 clinical trial of PROHEMA in adult patients undergoing double umbilical cord blood transplantation for the treatment of hematologic malignancies. Following the completion of this second review by the iDMC, which is expected to include clinical data from approximately 12 PROHEMA patients and 8 control patients, the Company intends to provide an update on the PUMA study. In its first data review, conducted in August 2014, the iDMC did not identify any safety signals and supported continuation of the study.

Full data on the primary efficacy endpoint from the PUMA study are expected in mid-2015. The primary endpoint is based on a categorical analysis of neutrophil engraftment, and is designed to demonstrate with statistical significance that 70% of patients 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 patient to destroy malignant cells and to prevent rejection of the donor hematopoietic cells, has been established as 26 days for patients receiving myeloablative conditioning and 21 days for patients receiving reduced-intensity conditioning. These pre-specified values are based on multi-center reports in the literature of historical median times to neutrophil engraftment in adult patients undergoing double umbilical cord blood transplantation in the United States. The PUMA study also includes a concurrent control arm to validate the pre-specified values of neutrophil engraftment and to provide context for interpretation of other clinical outcomes. The Company plans to assess multiple secondary endpoints and outcomes that contribute significantly to patient morbidity and mortality to guide its clinical development strategy including key measures of hematopoietic reconstitution, such as time to neutrophil and platelet engraftment, distribution of engraftment times and overall rates of graft failure, as well as viral and bacterial infections, graft versus host disease and treatment-related mortality.

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 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 stem cell, or HSC, therapeutic, which is currently in clinical development for patients undergoing HSC transplantation. 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 therapeutic potential of PROHEMA®, 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. These risks and uncertainties include, but are not limited to, the risks that the results of PROHEMA observed in prior preclinical and clinical development may not be replicated or may cause unanticipated adverse effects in current or subsequent clinical trials of PROHEMA, 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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