

Fate Therapeutics Announces Key 2015 Objectives for the Advancement of Programmed Cellular Therapeutics Pipeline

Primary Endpoint Read-outs from Adult PUMA and Pediatric PROMPT Studies of PROHEMA in Hematologic Malignancies Expected in mid-2015

Topline Data from Pediatric PROVIDE Study of PROHEMA in Rare Inherited Metabolic Disorders Expected in 2015

IND Filing for New Programmed Mobilized Peripheral Blood Candidate Planned in 2015

SAN DIEGO, Jan. 12, 2015 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (Nasdaq:FATE), a biopharmaceutical company engaged in the development of programmed cellular therapeutics for the treatment of severe, life-threatening diseases, today announced key pipeline objectives for 2015.

"Building upon our solid progress in 2014, we are poised to reach multiple clinical data read-outs throughout 2015 and establish the disease-transforming potential of PROHEMA® across a wide range of blood cancers and rare genetic disorders," said Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of Fate Therapeutics. "In late 2014, we reported favorable interim clinical data from our ongoing Phase 2 PUMA study and exciting preclinical findings with our newly-discovered small molecule modulator combination, further strengthening our conviction in the therapeutic potential of *ex vivo* programmed hematopoietic cells. Continuing this momentum, we have begun to advance a programmed mobilized peripheral blood candidate towards a planned 2015 IND filing, and are actively researching novel mechanisms to enhance the immunotherapeutic potential of CD34+ and T cells. We believe we are well-positioned in the coming year to expand our programmed hematopoietic cellular therapeutics pipeline and to leverage our *ex vivo* programming approach to pursue significant therapeutic opportunities."

Key 2015 Pipeline Objectives

- **Report Full Data on the Primary Efficacy Endpoint in mid-2015 from the Phase 2 PUMA Study of PROHEMA.** Fate Therapeutics is currently enrolling adult subjects in its Phase 2 PUMA study of PROHEMA, an *ex vivo* programmed hematopoietic cellular therapeutic derived from umbilical cord blood. The PUMA study is a randomized, controlled, open-label clinical trial designed to enroll 60 adult subjects undergoing double umbilical cord blood transplantation for the treatment of blood cancers. The primary objective of the study is to evaluate neutrophil engraftment, which is essential for the successful reconstitution of a new blood and immune system. The study will also assess other key clinical endpoints that contribute to the overall morbidity and mortality of hematopoietic stem cell transplantation (HSCT) including platelet engraftment, engraftment failure, bacterial infections, viral reactivation, graft-versus-host disease, relapse, non-relapse mortality and disease-free survival. The Company expects to report full data on the primary endpoint in mid-2015.
- **Report Topline Data in 2015 from the Phase 1b PROVIDE Study of PROHEMA.** Fate Therapeutics is currently initiating the clinical investigation of PROHEMA as a cellular enzyme replacement therapy for pediatric patients with inherited metabolic disorders (IMDs). The Company's Phase 1b PROVIDE study is an open-label clinical trial designed to enroll 12 pediatric subjects undergoing single umbilical cord blood transplantation. Sixteen different types of lysosomal and peroxisomal storage diseases, such as Hurler and Hunter syndromes, Krabbe disease and various other leukodystrophies, qualify for treatment under the study's inclusion criteria. The primary objective of the study is to evaluate neutrophil engraftment. The study will also include a series of neuro-imaging and neuro-cognitive assessments to explore the potential of the programmed hematopoietic cells to provide long-term replacement of an otherwise deficient enzyme to the central nervous system through a process known as cross-correction. In *in vivo* murine models of allogeneic HSC transplantation, Fate Therapeutics has demonstrated that the use of programmed CD34+ cells, as compared to unmodulated cells, led to a significant increase both in the engraftment of donor HSCs and in the donor-derived expression of enzyme in the brain. The Company expects to report topline data from the PROVIDE study in 2015.
- **Report Full Data on the Primary Efficacy Endpoint in mid-2015 from the Phase 1b PROMPT Study of PROHEMA.** The Company is currently enrolling pediatric subjects in its Phase 1b PROMPT study of PROHEMA. The PROMPT study is an open-label clinical trial designed to enroll 18 pediatric subjects undergoing single umbilical cord blood transplantation for the treatment of blood cancers. The primary objective of the study is to evaluate neutrophil engraftment. The Company expects to report full data on the primary endpoint in mid-2015.
- **File an Investigational New Drug Application in 2015 for an *Ex Vivo* Programmed Mobilized Peripheral Blood Candidate.** Preclinical data presented by company scientists at the 56th Annual Meeting and Exposition of the American Society of Hematology in December 2014 showed that the newly-identified small molecule modulator combination of

FT1050 and FT4145 enhances the biological properties and the *in vivo* therapeutic potential of mobilized peripheral blood. The programming of CD34+ cells with FT1050 and FT4145 resulted in a 60-fold increase in CXCR4 gene expression levels and a statistically significant increase in engraftment as compared to unmodulated cells, and T-cells programmed with FT1050 and FT4145 were found to have a 66% reduction of cell-surface protein expression of ICOS, a key T-cell activation marker, and a statistically significant reduction in proliferation rates relative to unmodulated cells. Fate Therapeutics expects to file an Investigational New Drug application in 2015 to assess the safety and efficacy of programmed mobilized peripheral blood in subjects undergoing allogeneic HSCT for the treatment of hematologic malignancies.

- **Advance Preclinical Pipeline of Programmed Cellular Therapeutics.** Through internal research efforts, Fate Therapeutics continues to target biological mechanisms that are therapeutically-relevant for modulation and to pursue several attractive opportunities for programmed cellular candidates with disease-transforming potential, including programmed CD34+ cells and programmed T-cells for the regulation of the immune system. In 2015, Fate Therapeutics aims to nominate at least one programmed hematopoietic cellular candidate for further development.

Fate Therapeutics to Present at 7th Annual Biotech Showcase

Dr. Weyer will present today an overview of the Company's programs at the 7th Annual Biotech Showcase conference at 11:30 am PST in San Francisco, California. A live webcast of the presentation can be accessed under "Events & Presentations" in the Investors and Media section of the Company's website at www.fatetherapeutics.com. An archived replay of the webcast will be available on the Company's website for 30 days after the conference.

About PROHEMA®

PROHEMA® is an *ex vivo* programmed hematopoietic cellular therapeutic derived from umbilical cord blood. PROHEMA is produced by modulating the biological properties of hematopoietic stem cells (HSCs) and T-cells of umbilical cord blood *ex vivo* using the small molecule FT1050 (16,16 dimethyl prostaglandin E₂, or dmPGE₂). The proprietary modulation process 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-derived source of hematopoietic cells for use in allogeneic hematopoietic stem cell transplantation (HSCT) to treat severe, life-threatening hematologic malignancies and inherited metabolic disorders. In 2010, the FDA granted PROHEMA orphan designation for the enhancement of HSC engraftment in patients undergoing umbilical cord blood transplantation.

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 inherited immune and blood disorders. The procedure involves transferring donor-derived hematopoietic cells, including stem cells and T-cells, 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 - HSCs reconstitute and replace the patient's blood and immune system, and T-cells act as an immunotherapeutic to eliminate residual malignancy. More than 20,000 allogeneic HSCTs are performed annually worldwide in an effort to achieve long-term disease-free remission and/or functional cures.

About Fate Therapeutics, Inc.

Fate Therapeutics is a clinical-stage biopharmaceutical company engaged in the development of programmed cellular therapeutics for the treatment of severe, life-threatening diseases. The Company's approach utilizes established pharmacologic modalities, such as small molecules, to program the fate and function of cells *ex vivo*. The Company's lead product candidate, PROHEMA®, is an *ex vivo* programmed hematopoietic cellular therapeutic, which is currently in clinical development for the treatment of hematologic malignancies and rare genetic disorders in patients undergoing hematopoietic stem cell transplantation (HSCT). The Company is also using its proprietary induced pluripotent stem cell platform to develop *ex vivo* reprogrammed hematopoietic and myogenic cellular therapeutics. 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 programmed mobilized peripheral blood, the Company's plans with respect to PROHEMA and other product candidates, anticipated clinical and development milestones (including the timing and results of ongoing and planned clinical trials, and the availability of clinical data and results), and the plans of the Company to undertake certain research and development activities, including the evaluation of the *ex vivo* programming of CD34+ cells and T-cells. 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 in current or subsequent clinical trials of PROHEMA, 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 effects or events or other negative results that may be observed in these trials), or the risk that we are unable to conduct or complete preclinical and clinical activities necessary to advance any additional hematopoietic cellular therapeutic product candidates, including any candidates derived from mobilized peripheral blood, CD34+ cells or T-cells. 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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