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Fate Therapeutics Announces FDA Clearance of IND Amendment for Clinical Development of PROHEMA(R) in Pediatric Patients

Phase 1b PROMPT Study in Hematologic Malignancies Expected to Begin in Mid-2014

SAN DIEGO, April 23, 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 that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug Application (IND) amendment to evaluate PROHEMA® in pediatric patients undergoing hematopoietic stem cell (HSC) transplantation for the treatment of hematologic malignancies. The FDA's clearance of the IND amendment allows the Company to expand its clinical investigation of PROHEMA®, which to date has only been administered to adults, in pediatric patients as young as one year of age. The Company plans to initiate enrollment of the "PROMPT" (PROHEMA® for the treatment of hematologic Malignancies in PediaTric patients undergoing single umbilical cord blood transplantation) study, which is designed to enroll up to 18 patients, between the ages of 1 and 18, at three leading U.S. pediatric transplant centers in mid-2014.

"Each year, over 3,500 children in the U.S. are diagnosed with leukemia, many of whom may ultimately require HSC transplantation," commented Pratik Multani, M.D., M.S., Chief Medical Officer of Fate Therapeutics. "Building upon our encouraging clinical experience with PROHEMA® in adult patients, we look forward to expanding our clinical program to pediatric patients with life-threatening forms of leukemia and other hematologic malignancies. Our goal is to deliver a pharmacologically-optimized HSC therapeutic that can support rapid and durable hematologic and immunologic reconstitution, and enable the curative potential of HSC transplantation in patients across a wide range of ages and a broad spectrum of life-threatening malignant and rare genetic disorders."

PROHEMA® (16, 16-dimethyl prostaglandin E2, or dmPGE2, modulated cord blood), which is currently being evaluated in a Phase 2 clinical trial in adults, is the Company's lead pharmacologically-modulated HSC therapeutic. In 2010, the FDA granted PROHEMA® orphan designation for the enhancement of stem cell engraftment in patients undergoing allogeneic HSC transplantation. The PROMPT study is an open-label Phase 1b clinical trial of PROHEMA® in pediatric patients undergoing single umbilical cord blood transplantation for the treatment of various hematologic malignancies, such as acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML),following myeloablative conditioning. Consistent with the recently initiated Phase 2 clinical trial in adults, the manufacture of PROHEMA® in the PROMPT study will utilize the Company's nutrient-rich media formulation, which has been shown in *in vivo* preclinical studies to improve HSC viability as well as HSC engraftment by more than two-fold as compared to a standard cell processing media. The primary endpoint of the PROMPT study is safety as assessed by neutrophil engraftment. The study will also evaluate various parameters of efficacy including additional measures of neutrophil engraftment, 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. 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, 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, 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, the PROMPT study. 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 our PROMPT clinical trial, or other current or subsequent clinical trials, of PROHEMA®, and that PROHEMA® may not produce the therapeutic benefits suggested by the results observed in our prior clinical development, or may cause other unanticipated adverse effects, in current or subsequent clinical trials, 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 PROMPT study, or any adverse events or other negative results that may be observed in the PROMPT 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-K for the fourth quarter and year ended December 31, 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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