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Fate Therapeutics Submits IND Application for the Clinical Development of PROHEMA(R) in Inherited Metabolic Disorders

SAN DIEGO, June 30, 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 it has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) for the clinical development of PROHEMA in pediatric patients with inherited metabolic disorders undergoing hematopoietic stem cell transplantation (HSCT). Pending FDA review of the IND application, the Company plans to initiate a Phase 1b clinical trial in pediatric patients who have inherited metabolic disorders where enzyme replacement therapy is not a viable treatment option, including certain patients with central nervous system involvement.

"Building upon the clinical development of PROHEMA in adult and pediatric patients with hematologic malignancies, we believe there are significant opportunities for development of pharmacologically-optimized HSC therapeutics in rare genetic disorders," said Christian Weyer, M.D., M.A.S., President and Chief Executive Officer of Fate Therapeutics. "Submission of this IND application to support the clinical evaluation of PROHEMA in inherited metabolic disorders reflects our commitment to improving patient outcomes across a broad spectrum of malignant and non-malignant conditions."

Inherited metabolic disorders include a range of genetic enzyme deficiencies that interfere with critical metabolic pathways necessary to maintain normal organ function. In many of these disorders, the enzyme deficiency leads to cellular accumulation of toxic intermediates within the brain, causing progressive neurological damage that cannot be addressed with enzyme replacement therapy. For those inherited metabolic disorders, which include over 20 lysosomal and peroxisomal storage diseases such as Hurler and Hunter syndromes, Krabbe disease and multiple leukodystrophies, allogeneic HSCT holds potential as a one-time, definitive therapy. Following allogeneic HSCT, donor-derived cells can migrate to and engraft in the brain, providing a long-term supply of an otherwise deficient enzyme to the central nervous system in a process known as cross-correction. In *in vivo* murine models of allogeneic HSCT, Fate Therapeutics has demonstrated that the use of PROHEMA, as compared to unmanipulated hematopoietic stem cells (HSCs), led to a significant increase both in the engraftment of donor HSCs and in the donor-derived expression of enzyme in the brain.

About PROHEMA

PROHEMA® (16, 16-dimethyl prostaglandin E2, or dmPGE2, modulated cord blood) 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, including small molecules and therapeutic proteins, to treat orphan diseases. 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 HSC product candidate, PROHEMA, in Phase 2 clinical development for hematologic malignancies, while 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, including in pediatric patients who have inherited

metabolic disorders, and our clinical development plans for PROHEMA, including our ability to initiate and conduct our planned Phase 1b clinical trial in this patient population. 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 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 preclinical and 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 the uncertainty of the FDA IND review process and other regulatory requirements, additional information that may be requested or additional obligations, including changes to our clinical development plans or protocols, that may be imposed by the FDA as a condition to our initiation or continuation of clinical trials with PROHEMA, any difficulties or delays in patient enrollment in clinical trials, or any adverse events or other negative results that may be observed in clinical 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 first quarter ended March 31, 2014, 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.

CONTACT: Paul Cox, Stern Investor Relations, Inc.

212.362.1200, paul@sternir.com

Fate Therapeutics

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