February 26, 2014

Fate Therapeutics Announces Observed Effects of Pharmacologic Modulation on T Cell Compartment From Its Phase 1b Study of PROHEMA(R)

SAN DIEGO, Feb. 26, 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 release of new data on the observed effects of *ex vivo* pharmacologic modulation on CD8+ T cells and immune reconstitution from its previously-completed Phase 1b clinical trial of PROHEMA® (16, 16-dimethyl prostaglandin E2, or dmPGE2, modulated cord blood) in adult patients undergoing hematopoietic stem cell (HSC) transplantation for hematologic malignancy (the ProHema-01 trial). Researchers affiliated with Harvard Medical School performed an analysis of the CD8+ T cell compartment using patient samples from the ProHema-01 trial. At Day 100, subjects who received PROHEMA® and an unmanipulated cord blood unit (n=12) showed a two-fold increase in the percentage of naïve and early memory T cell fraction within the CD8+ T cell compartment as compared to subjects who received two unmanipulated cord blood units (n=9). These naïve and early memory CD8+ T cell populations are believed to play a key role in promoting immune reconstitution and viral immunity following cord blood transplantation. These findings were recently published in Blood Cancer Journal (Li, L. et. al. Blood Cancer Journal 2014).

"In addition to the well-established effect of dmPGE2 on enhancing the engraftment properties of hematopoietic stem cells, our molecular characterization and immunological assessments provide new evidence that dmPGE2 can also significantly improve the functional properties of T cells contained within human umbilical cord blood," stated Dr. Vicki Boussiotis, M.D., Ph.D., Professor, Department of Medicine, Harvard Medical School, and senior author on the Blood Cancer Journal publication. "Enhancing the survival and immunological properties of T cells, and in particular those of naïve CD8+ T cells, may have significant therapeutic implications for harnessing immune memory in the context of both pathogen- and tumor-specific immunity."

Consistent with these reported immunomodulatory effects, low rates of viral reactivation were observed in the ProHema-01 trial. Specifically, cytomegalovirus (CMV) reactivation occurred in only two of 12 PROHEMA® subjects (17%), with no cases of CMV disease. In addition, no cases of Epstein-Barr virus (EBV)-associated post-transplant lymphoproliferative disorders (PTLD) were observed. These observations compare favorably to rates of CMV reactivation and EBV-associated PTLD reported in the literature of 36-56% and up to 16%, respectively.

"The functional properties of both hematopoietic stem cells and T cells are critical determinants of patient outcomes following allogeneic umbilical cord blood transplantation," commented Pratik Multani, M.D., M.S., Chief Medical Officer of Fate Therapeutics. "These novel scientific and clinical observations raise the possibility that T cell-related mechanisms may also be enhanced using *ex vivo* pharmacologic modulation strategies. We look forward to evaluating patient outcomes related to dmPGE2-mediated immunomodulatory effects in our planned Phase 2 clinical trial of PROHEMA®."

PROHEMA® is currently in clinical development for use in adult patients with hematologic malignancies undergoing double umbilical cord blood transplantation.Following an optimization of the PROHEMA® manufacturing process, the Company expects to resume enrollment of its Phase 2 clinical trial (the ProHema-03 Trial) in the first half of 2014, with the goal of generating full data on the primary and major secondary endpoints related to engraftment in mid-2015.

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 study 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 study, 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 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, which is 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 our programs for the modulation of adult stem cells to treat orphan diseases, the ability of dmPGE2 to improve the functional properties of T cells within human umbilical cord blood, the ability of *ex vivo* pharmacologic modulation of adult stem cells to enhance T cell-related mechanisms, the potential therapeutic benefits of enhancing the survival and immunological properties of T cells, our ability to resume enrollment of the ProHema-03 trial in the first half of 2014 following an optimization of the PROHEMA® manufacturing process, and our ability to generate full data on the primary and major secondary endpoints related to engraftment in mid-2015. 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 observed in our ProHema-01 trial may not be replicated in our ProHema-03 trial or other subsequent clinical trials of PROHEMA®, PROHEMA® may not produce the therapeutic benefits suggested by the results observed in our ProHema-01 trial or may cause other unanticipated adverse effects in subsequent clinical trials, or we may cease or delay any of our 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 resumption or continuation of the ProHema-03 trial, any inability to obtain an adequate clinical supply of PROHEMA®, any delays in enrollment of our ProHema-03 trial, and any negative results following resumption of the ProHema-03 trial. 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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