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Fate Therapeutics Announces Promising Data From Phase 1B Study of ProHema at the 2011 American Society of Hematology Annual Conference

Data Support the Potential Benefit of a Novel Ex Vivo Cell Modulation Approach to Improving Engraftment in Patients Undergoing Umbilical Cord Blood Transplantation

San Diego, CA – Fate Therapeutics, Inc. announced today promising clinical results from a Phase 1b trial of ProHema (FT1050-enhanced umbilical cord blood) as part of double-umbilical cord blood (UCB) transplants in adult patients with hematologic malignancies who have undergone reduced-intensity conditioning therapy. The data are being presented at the 53rd annual American Society of Hematology (ASH) meeting, being held December 10-13, in San Diego, California (Abstract Number: 653; entitled, "FT1050 (16,16-dimethyl Prostaglandin E2)-Enhanced Umbilical Cord Blood Accelerates Hematopoietic Engraftment After Reduced Intensity Conditioning and Double Umbilical Cord Blood Transplantation"). ProHema is a first-in-class therapeutic candidate, consisting of pharmacologically-enhanced hematopoietic stem cells (HSC), designed to improve HSC support during the normal course of a stem cell transplant for the treatment of patients with hematologic malignancies.

The Phase 1b double-UCB study conducted at the Dana-Farber Cancer Institute and the Massachusetts General Hospital achieved its primary objective of demonstrating safety and tolerability of ProHema based upon patient engraftment by Day 42 with greater than 5% chimerism of the ProHema unit. In addition, of the twelve subjects presented in the abstract that received a ProHema unit and an untreated unit, the median time to neutrophil recovery (> 500 cells/μL) was 17.5 days, which compares favorably to a median of 21 days for a historic control group of similarly treated subjects at the Dana-Farber Cancer Institute (n=53). In addition, the ProHema unit was the dominant source of hematopoiesis in ten of the twelve subjects, suggesting that treatment with ProHema may confer preferential engraftment.

"These clinical trial data support Fate's novel therapeutic approach for the development of stem cell biology-based medicines," said Pratik Multani, M.D., Senior Vice President, Clinical Development at Fate Therapeutics. "We believe these clinical observations represent the first evidence that the ex vivo pharmacologic modulation of hematopoietic stem cells has the potential to improve patient outcomes, and we look forward to rapidly advancing ProHema into broader clinical investigation."

There were no instances of primary or secondary graft failure in the twelve subjects. The adverse events associated with the infusion of the ProHema unit appeared to be no greater than the background expected rate associated with cord blood infusion. The events consisted of five Grade 1/2 infusion-related events of chills, flushing, abdominal pain, or cough in 4 subjects. In addition, one subject experienced transient Grade 4 ST- elevation following infusion and evidence of myocardial ischemia by cardiac troponin assay. To date, two cases of Grade 2 acute graft-versus-host disease (GvHD) have been observed in the first 100 days, and one subject developed NIH mild chronic GvHD. Currently, treatment related mortality is 8% (one subject). One subject has relapsed, while the remaining ten subjects are alive without relapse with a median follow-up of approximately 8.5 months.

"ProHema appears to offer the potential to improve clinical outcomes for patients undergoing double-UCB transplantation," said Corey Cutler M.D., M.P.H., F.R.C.P.C., associate professor of medicine at the Dana-Farber Cancer Institute and Harvard Medical School and principal investigator of the Phase 1b clinical study. "Given the competitive engraftment dynamic of double-UCB transplantation, the clinical data suggest that the ProHema unit was able to preferentially engraft over the untreated cord blood unit. While further investigation is needed to confirm this finding, these data open the possibility for clinicians to treat the best-matched unit to encourage more favorable patient outcomes."

Fate Therapeutics is exploring the benefits of ProHema in other settings of HSC transplantation. The Company has submitted to the FDA a clinical protocol to evaluate ProHema in a single-cord blood allogeneic transplant setting, and intends to begin enrolling patients into that study within the next three months.

About Hematopoietic Stem Cell Support
Intensive chemotherapy, radiation and/or immunotherapy are often used to treat patients with hematologic malignancies, such as leukemia and lymphoma, who have not been cured with conventional treatment. These high-dose regimens, designed to kill the cancer cells, will also often destroy the patient's normal blood and immune systems in the process. Therefore, hematopoietic reconstitution through the administration of HSCs is necessary to restore normal bone marrow function. In addition, the immune cells generated by the HSCs, in some cases, play a role in eradicating cancer cells. Possible sources of HSCs include bone marrow, peripheral blood or umbilical cord blood. The entire procedure is often referred to as hematopoietic stem cell support.

About *Ex Vivo* HSC Modulation

UCB transplantation relies on a small number of HSCs to restore hematopoiesis. Even with double-UCB transplantation, engraftment times are prolonged and immune reconstitution delayed. Preclinical studies conducted by Leonard Zon, M.D., Grousbeck Professor in Hematology/Oncology at the Children's Hospital Boston and a Scientific Founder of Fate Therapeutics, have suggested that the *ex vivo* treatment of HSCs with certain prostaglandins can enhance the effective cell dose of HSCs – without stem cell expansion or differentiation of HSCs to committed progenitors – and improve the time to, and durability of, engraftment (North TE, Nature, 2007, 447:1007-1011). Using both murine and human-xenograft model systems, the mechanisms of action have been demonstrated to involve improved homing via CXCR4-SDF-1, increased proliferation and entry into the cell cycle, and decreased rates of apoptosis (Goessling 2009; Hoggatt 2009; Goessling 2011).