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## **Fate Therapeutics Announces Emerging Data From Proof-Of-Concept FT1050 Clinical Trial and Receives Orphan Drug Designation**

### **Encouraging Phase 1b Clinical Data Presented at 2011 BMT Tandem Meetings**

**San Diego, CA – February 21, 2011** – [Fate Therapeutics, Inc.](http://www.fatetherapeutics.com) presented encouraging preliminary data from an ongoing Phase 1b clinical trial of FT1050 at the 2011 BMT Tandem Meetings in Honolulu, Hawaii (Abstract Number: 198; entitled, “Ex Vivo Treatment of Hematopoietic Stem Cells with 16,16-dimethyl Prostaglandin E2 (FT1050) Improves Engraftment and Hematopoietic Reconstitution”).

“We are excited by the emerging clinical trial data that support the future of *ex vivo*-based therapeutics for stem cell driven therapies. More importantly, our results bring us one step closer to potentially having a meaningful impact on patients with life-threatening conditions,” said John Mendlein, Ph.D., executive chairman of Fate Therapeutics.

The goal of the Phase 1b trial, which is being conducted at the Dana-Farber Cancer Institute and Massachusetts General Hospital, is to determine the safety and tolerability of introducing FT1050 during the standard course of dual umbilical cord blood transplant in adult patients with hematologic malignancies, such as leukemia and lymphoma, who have undergone nonmyeloablative conditioning therapy. Fate Therapeutics is developing FT1050 to improve the overall efficiency of hematopoietic stem cell (HSC) support by enhancing HSC homing to and proliferation in the bone marrow.

“Until the hematopoietic system begins to function again in the bone marrow, patients are susceptible to life-threatening infections and other complications,” said Corey Cutler M.D., M.P.H., F.R.C.P.C., assistant professor of medicine at the Dana-Farber Cancer Institute and Harvard Medical School and principal investigator of the clinical study. “The ability to improve the speed and quality of engraftment while minimizing graft versus host disease is of utmost importance to improving clinical outcomes and helping thousands of patients who need this procedure.”

In the ongoing Phase 1b clinical trial, after a reduced-intensity conditioning regimen, each patient receives two umbilical cord blood units for hematopoietic reconstitution: one treated *ex vivo* at the point-of-care with FT1050 and one untreated. Fifteen subjects of an anticipated 21 have been enrolled to date, with the last six having received an umbilical cord blood unit using the current FT1050 treatment protocol designed to enhance activity; the first nine patients received an umbilical cord blood unit using an earlier version of the FT1050 treatment protocol designed to assess safety. The investigators evaluated the safety of FT1050 as well as the time to initial hematopoietic reconstitution, and which cord blood unit ultimately contributed most to blood count recovery.

The average time to engraftment for the six patients who were treated under the current protocol was 18.5 days compared to a historic average of approximately 21 days. In addition, five of these six patients engrafted with the FT1050 treated cord blood unit, suggesting that FT1050 may confer preferential engraftment. In all 15 patients, the safety profile did not appear to differ from that of a standard double umbilical cord transplant. To date, only one patient has experienced Grade 2 or higher acute graft versus host disease. Ten of 15 patients remain alive and disease-free. Accrual is ongoing.

In addition, Fate Therapeutics announced today that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to FT1050 for the *ex vivo* treatment of human allogeneic hematopoietic stem cells to enhance stem cell engraftment by treating neutropenia, thrombocytopenia, lymphopenia and anemia. The Company has also received a positive recommendation by the Committee for Orphan Medicinal Products for orphan designation in the European Union.

“The orphan drug status, combined with encouraging preliminary Phase 1b clinical trial results and a strong intellectual property portfolio, give us confidence in continuing to develop FT1050 for patients who have life threatening blood cancers and disorders,” said Pratik Multani, M.D., M.S., vice president of clinical development at Fate Therapeutics.

### **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. Also, 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.