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Fate Therapeutics Initiates Phase 2 PROTECT Study of ProTmune™ for Prevention of Acute Graft-versus-Host Disease

Independent Data Monitoring Committee Conducts Phase 1 Safety Review and Unanimously Recommends Opening of Phase 2 Enrollment

First Seven Subjects Receiving ProTmune Clear Phase 1 Safety Objectives of Engraftment and Survival at Day 28

Phase 1 Day 100 Acute GvHD Data Expected to be Presented at 2017 ASH Annual Meeting

SAN DIEGO, Sept. 18, 2017 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (NASDAQ:FATE), a biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders, announced today that the Company initiated enrollment in the Phase 2 stage of PROTECT, a combined open-label Phase 1 / blinded Phase 2 clinical trial of ProTmune™ for the prevention of acute graft-versus-host disease (GvHD) in patients with hematologic malignancies undergoing matched unrelated donor hematopoietic cell transplantation (HCT). Thirteen U.S. centers are currently open for enrollment in the Phase 2 stage of PROTECT.

"Acute GvHD is the leading cause of early morbidity and mortality in patients undergoing allogeneic transplant. We are excited to initiate the randomized, controlled and blinded Phase 2 stage of PROTECT and assess the potential of ProTmune to deliver transformative benefits to cancer patients," said Chris Storgard, M.D., Chief Medical Officer of Fate Therapeutics. "We thank the study's independent data monitoring committee for its Phase 1 data review. Once all seven Phase 1 subjects progress to Day 100 post-HCT, we expect to present ProTmune Day 100 efficacy data, including acute GvHD, cancer relapse and survival, at the 2017 American Society of Hematology annual meeting."

The Phase 2 stage is assessing the safety and efficacy of ProTmune in 60 subjects, where subjects are being randomized, in a 1:1 ratio, to receive either ProTmune or a conventional matched unrelated donor mobilized peripheral blood cell graft. The primary efficacy endpoint of PROTECT is incidence of acute GvHD by Day 100 post-HCT, where prospective clinical studies have shown that 40% to 80% of patients undergoing matched unrelated donor transplant experience Grades 2-4 acute GvHD. There are currently no approved preventive therapies and very few treatment options for acute GvHD.

PROTECT Phase 1 Safety & Manufacturing Data

On September 14, 2017, the study's four-member independent data monitoring committee conducted a review of all available Phase 1 data. Based on its review, the committee unanimously recommended initiation of the randomized, controlled and blinded Phase 2 stage of PROTECT.

The Phase 1 review by the committee included data on the first seven subjects receiving ProTmune. Underlying hematologic diseases included three subjects with acute lymphoblastic leukemia (ALL), three with acute myeloid leukemia (AML) and one with myelodysplastic syndrome (MDS). All subjects met the Day 28 safety objectives of neutrophil engraftment and survival, and reached Day 28 without any events of graft failure or serious adverse events related to ProTmune. The median time to neutrophil engraftment was 18 days [14-22 days].

ProTmune was successfully manufactured at four clinical sites. Cell viability and CD34+ cell recovery (mean +/- SD) were 87.7 +/- 7.5% and 90.5 +/- 14.6%, respectively. The cell-surface protein CXCR4 (mean +/- SD), a key pharmacological biomarker of product potency, was expressed on 67.7 +/- 10.2% of CD34+ cells as compared to approximately 5% of CD34+ cells contained in a conventional hematopoietic cell graft.

About Acute Graft-versus-Host Disease
Acute GvHD is a severe immunological disease that commonly arises in patients during the first weeks following allogeneic HCT when the newly-transplanted donor immune cells attack the patient's tissues and organs, resulting in a potentially fatal immune system reaction. Prospective clinical studies have shown that 40% to 80% of patients undergoing matched unrelated donor transplant experience Grades 2-4 acute GvHD, with most incidents occurring by Day 60 post-HCT despite the use of standard prophylaxis regimens. The disease is the leading cause of early morbidity and mortality in matched unrelated donor transplant, where death directly attributable to acute GvHD or its treatment occurs in 10% to 20% of

patients. There are currently no approved preventive therapies and very few treatment options for acute GvHD.

About ProTmune™
ProTmune™ is an investigational next-generation hematopoietic cell graft for the prevention of acute GvHD in patients undergoing allogeneic HCT. ProTmune is manufactured by pharmacologically modulating a donor-sourced, mobilized peripheral blood graft *ex vivo* with two small molecules (FT1050 and FT4145) to enhance the biological properties and therapeutic function of the graft. ProTmune has been granted Orphan Drug and Fast Track Designations by the U.S. Food and Drug Administration, and Orphan Medicinal Product Designation by the European Medicines Agency.

About Allogeneic Hematopoietic Cell Transplantation
There are approximately 30,000 allogeneic HCT procedures performed globally each year according to the Center for International Blood and Marrow Transplant Research. The procedure is performed with curative intent most often for patients with acute leukemias and myelodysplastic syndromes. While long-term curative rates are high for patients achieving disease-free survival at two years, patients face a multitude of life-threatening complications, including GvHD and cancer relapse, during the initial weeks and months following allogeneic HCT. In fact, the GvHD-free, relapse-free survival (GRFS) rate is only about 30% during the first year following allogeneic HCT.

About Fate Therapeutics, Inc.
Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's hematopoietic cell therapy pipeline is comprised of NK- and T-cell immuno-oncology programs, including off-the-shelf product candidates derived from engineered induced pluripotent cell lines, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation and to promote immune tolerance in patients with autoimmune disease. Its adoptive cell therapy programs are based on the Company's novel *ex vivo* cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells. 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 and market potential of ProTmune™, the Company's progress and plans for its clinical investigation of ProTmune, the ability of ProTmune to prevent, or reduce the incidence or severity of, graft-versus-host disease, severe infections, disease relapse or mortality, the potential safety of ProTmune in the treatment of diseases, the timing and success of the Company's PROTECT clinical trial, including the Company's ability to generate Day 100 efficacy data from the Phase 1 stage of the trial and the timing thereof, and the Company's ability to enroll patients in, and conduct, the Phase 2 stage of the trial. 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 risk of cessation or delay of planned development and clinical activities for a variety of reasons (including any delay in enrolling patients in clinical trials, or the occurrence of any adverse events or other results that may be observed during development), the risk that results observed in prior preclinical studies of ProTmune may not be replicated in subsequent studies or clinical trials, the risk that ProTmune may not produce therapeutic benefits or may cause other unanticipated adverse effects, and the risk that the Company may allocate its financial and other resources to programs or product candidates that ultimately have less therapeutic or commercial potential than other product opportunities. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's 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 most recently filed periodic report and, from time to time, in the Company's other investor communications. The Company is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

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