

## Fate Therapeutics Announces Day 100 Clinical Results from Phase 1 Stage of PROTECT Trial of ProTmune™ and Initiation of Phase 2 Stage

*All Subjects Achieved Day 100 Relapse-free Survival*

*All Incidents of Day 100 Acute GvHD Responded to Steroid Treatment*

*Randomized, Controlled and Double-Blinded Phase 2 Stage of PROTECT Now Enrolling*

SAN DIEGO, Dec. 11, 2017 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (NASDAQ:FATE), a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders, announced today Day 100 clinical data from the Phase 1 stage of its PROTECT clinical trial of ProTmune™, the Company's next-generation hematopoietic cell graft for patients with hematologic malignancies. All seven subjects receiving ProTmune remained alive and relapse-free during the first 100 days following hematopoietic cell transplantation (HCT). Three of the seven subjects experienced acute graft-versus-host disease (GvHD) during the first 100 days following HCT. Each of these three subjects responded to standard-of-care steroid treatment with a median time to resolution of the maximum GvHD grade of 7 days [range: 5-8 days].

"The significant risk of GvHD limits broad application of allogeneic transplant due to uncertainty of its short- and long-term impact on the recipient. It occurs frequently with variable intensity and can be a devastating disease when unresponsive to treatment. The requisite extended use of immunosuppressive agents to treat GvHD compromises the anti-leukemia activity of the transplant procedure and can significantly increase the risk of cancer relapse and mortality while also placing patients at risk for opportunistic infection," said Richard Maziarz, M.D., Principal Investigator, Oregon Health Sciences University. "The administration of a hematopoietic cell graft that is optimized to attenuate T-cell alloreactivity and maintain the graft's anti-leukemia activity is a novel and highly-attractive therapeutic approach to decrease the risk and enhance the curative potential of allogeneic transplantation."

### PROTECT Phase 1 Day 100 Clinical Results

Clinical data from the Phase 1 stage of PROTECT were presented today by Dr. Maziarz during a poster session at the 59<sup>th</sup> American Society of Hematology Annual Meeting and Exposition. The Phase 1 stage included seven adult subjects with hematologic malignancies undergoing matched unrelated donor HCT following myeloablative conditioning. During the first 100 days following HCT, all seven subjects receiving ProTmune remained alive and relapse-free. Three of the seven subjects experienced acute GvHD during the first 100 days following HCT, all of whom responded to standard-of-care steroid treatment. The median time to resolution of the maximum GvHD grade was 7 days [range: 5-8 days]. There were no events of graft failure, and there were no ProTmune-related serious adverse events reported by investigators.

PROTECT Day 100 Clinical Data							
Subject	1	2	3	4	5	6	7
Hematologic Malignancy	MDS	AML	AML	ALL	ALL	ALL	AML
CD34+ cell dose (x10 <sup>6</sup> /kg)	10.3	4.6	10.9	4.8	3.2	3.0	9.4
CD3+ cell dose (x10 <sup>8</sup> /kg)	3.1	1.8	2.6	2.8	2.0	1.2	2.8
ProTmune-related SAEs	None	None	None	None	None	None	None
Day of Neutrophil Engraftment <sup>1</sup>	Day 14	Day 18	Day 22	Day 15	Day 16	Day 18	Day 19
Acute GvHD / Grade (CIBMTR)	None	None	Grade 2	None	Grade 2	Grade 3	None
<i>Treatment Responsive</i>	---	---	Yes	---	Yes	Yes	---
<i>Time to Resolution of Maximum Grade</i>	---	---	7 days	---	8 days	5 days	---
Cancer Relapse-free	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Survival	Yes	Yes	Yes	Yes	Yes	Yes	Yes

<sup>1</sup> As measured from the day following HCT

"The Day 100 clinical results from our Phase 1 stage of PROTECT support the unique therapeutic potential of ProTmune to reduce graft-versus-host disease and promote relapse-free survival. We are very encouraged by these initial clinical findings and the potential of ProTmune to deliver transformative benefits to cancer patients," said Chris Storgard, M.D., Chief Medical Officer of Fate Therapeutics. "The randomized, controlled and double-blinded Phase 2 stage of PROTECT is enrolling subjects at 14 U.S. centers of excellence. Given the high rates of morbidity and mortality underlying hematopoietic cell transplantation, we have also engaged the FDA, under our Fast Track designation for ProTmune, to discuss the necessary activities for product registration."

All subjects receiving ProTmune in the PROTECT Phase 1 stage are being followed for a period of two years following HCT. As of a November 29, 2017 data cut-off, all subjects remained relapse-free, and there were no events of graft failure and no serious adverse events related to ProTmune reported by investigators. Non-relapse mortality was reported in two subjects (Subject 1 on Day 228; Subject 3 on Day 151). Five of seven subjects remained on study with median time on study of 154 days [Day 106 — 254].

#### PROTECT Phase 2 Design

The Phase 2 stage of PROTECT is a randomized, controlled and double-blinded clinical trial assessing the safety and efficacy of ProTmune in up to 60 adult subjects with hematologic malignancies undergoing matched unrelated donor HCT following myeloablative conditioning. 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 cumulative incidence of Grades 2-4 acute GvHD by Day 100 following HCT, where prospective clinical studies have shown that 40% to 80% of patients undergoing matched unrelated donor transplant experience Grades 2-4 acute GvHD. Immunosuppressant treatments are effective in only about half of affected HCT patients and are associated with a marked increase in severe infections and cancer relapse. Additional endpoints, such as rates of cancer relapse, chronic GvHD, non-relapse mortality and overall survival, are also being assessed. Fourteen U.S. centers are currently open for enrollment in the Phase 2 stage of PROTECT.

#### **About Acute GvHD**

Acute graft-versus-host disease (GvHD) is a severe immunological disease that commonly arises in patients during the first weeks following allogeneic HCT when 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 following 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 FDA-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 graft-versus-host disease (GvHD) in patients undergoing allogeneic hematopoietic cell transplantation. ProTmune is manufactured by pharmacologically modulating a donor-sourced, mobilized peripheral blood graft *ex vivo* with two small molecules (FT1050 and FT4145) to decrease the morbidity and mortality of acute GvHD while maintaining the anti-leukemia activity 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 Commission.

#### **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](http://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, and the Company's product registration strategy for ProTmune including its ability to pursue accelerated registration. 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 and early-stage clinical trials 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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