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Fate Therapeutics Announces FDA Fast Track Designation for ProTmune™

Phase 1/2 Clinical Trial of ProTmune for Prevention of Acute GvHD and CMV Infection Now Open for Enrollment

SAN DIEGO, June 20, 2016 (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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ProTmune™ for the reduction of incidence and severity of acute graft-versus-host disease (GvHD) in patients undergoing allogeneic hematopoietic cell transplantation (HCT). In addition, the Company announced that its multi-center, randomized, controlled Phase 1/2 clinical trial of ProTmune in adult subjects with hematologic malignancies is open for patient enrollment.

"The Fast Track designation for ProTmune underscores the significant need to address life-threatening immunological conditions which compromise the curative potential of allogeneic hematopoietic cell transplantation," said Chris Storgard, M.D., Chief Medical Officer of Fate Therapeutics. "Acute graft-versus-host disease is a leading cause of morbidity and mortality in allogeneic HCT recipients. There is no approved preventive therapy, and current treatments suppress immune function and place high-risk immunocompromised patients at even greater risk for severe infections. We look forward to continuing to work with the FDA to rapidly advance our novel immunotherapy through the clinical development and regulatory processes, with the aim of bringing a transformative therapy to patients in an expedited time frame."

Fate Therapeutics is currently investigating ProTmune in an open-label Phase 1/2 clinical trial for the prevention of acute GvHD and cytomegalovirus (CMV) infection, both of which are leading causes of morbidity and mortality in patients undergoing HCT. The multi-center clinical trial design consists of an initial 10-subject, Phase 1 stage, during which all subjects undergoing allogeneic mobilized peripheral blood (mPB) HCT will receive ProTmune. Following an independent data monitoring committee safety review, a 60-subject, randomized, controlled Phase 2 stage is expected to enroll, during which subjects undergoing allogeneic mPB HCT will be assigned to receive either ProTmune or a conventional mPB cell graft in a 1:1 ratio.

The Fast Track Designation is designed to facilitate development and expedite review of experimental therapies that address the unmet medical needs of patients with serious conditions. Acute GvHD usually occurs within the first several months post-HCT when newly-transplanted donor immune cells recognize the patient's body as foreign and attack the patient's tissue. Despite the use of protocols to reduce the incidence of acute GvHD, up to 50 percent of HCT recipients still experience the debilitating disease. Additionally, only about half of patients with acute GVHD durably respond to its treatment. There are approximately 30,000 allogeneic HCT procedures performed globally each year according to the Center for International Blood and Marrow Transplant Research.

About ProTmune™
ProTmune™ is an investigational programmed cellular immunotherapy undergoing clinical development for the prevention of acute GvHD and CMV infection in patients undergoing allogeneic HCT. The cell therapy is produced by 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's immune cells. The programmed mobilized peripheral blood graft is adoptively transferred and administered to a patient as a one-time intravenous infusion.

About Fate Therapeutics, Inc.
Fate Therapeutics is a biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's cell therapy pipeline is comprised of immuno-oncology programs, including off-the-shelf NK- and T-cell cancer immunotherapies derived from engineered induced pluripotent cells, and immuno-regulatory programs, including hematopoietic cell immunotherapies for protecting the immune system of patients undergoing hematopoietic cell transplantation and for regulating autoimmunity. 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, and expected clinical trial design, for its clinical investigation of ProTmune, and the ability of ProTmune to prevent, or reduce the incidence or severity of, acute graft-versus-host disease and severe viral infections, including CMV infection. 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 initiating or 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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