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Fate Therapeutics Announces FDA Clearance of Investigational New Drug Application for ProTmune for Prevention of Acute GvHD and CMV Infection

Multi-Center, Randomized, Controlled Phase 1/2 Clinical Trial in Mobilized Peripheral Blood HCT to be Initiated in Mid-2016

SAN DIEGO, Jan. 26, 2016 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (NASDAQ:FATE), a biopharmaceutical company dedicated to the development of programmed cellular immunotherapeutics for cancer and immune disorders, announced today the U.S. Food and Drug Administration (FDA) has cleared the Company's investigational new drug (IND) application for ProTmune™, a programmed cellular immunotherapy consisting of donor-sourced mobilized peripheral blood cells which have been functionally modulated using two small molecules. The IND is now active and Fate Therapeutics plans to initiate a multi-center, randomized, controlled Phase 1/2 clinical trial in adult patients with hematologic malignancies undergoing mobilized peripheral blood (mPB) hematopoietic cell transplantation (HCT) in mid-2016.

"We are pleased to clear this important milestone with the FDA, and expect to initiate the clinical investigation of ProTmune in mid-2016 for the prevention of life-threatening complications that often compromise the curative potential of HCT," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "Programming donor immune cells *ex vivo* to enhance therapeutic function upon adoptive transfer is a highly-differentiated therapeutic paradigm, which is easily integrated into current clinical practice and avoids costly and time-consuming measures, such as genetic engineering, cell expansion and cell separation. We believe the use of ProTmune as the donor cell source for HCT can meaningfully improve patient outcomes, decrease hospital length of stay by mitigating use of in-hospital drug treatments, and substantially reduce the overall cost of care."

The primary objectives of the Phase 1/2 clinical trial are to evaluate safety and tolerability, and to assess the potential of ProTmune to prevent acute graft-versus-host disease (GvHD) and cytomegalovirus (CMV) infection, both of which are leading causes of morbidity and mortality in patients undergoing HCT. There are currently no approved therapies for the prevention of GvHD or CMV infection in patients undergoing allogeneic HCT, giving rise to a significant unmet medical need.

The clinical trial design consists of an initial 10-subject, Phase 1 stage, during which all subjects undergoing mPB HCT following myeloablative conditioning 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 mPB HCT following myeloablative conditioning will be assigned in a 1:1 ratio to receive either ProTmune or unmanipulated mPB cells. Two Endpoint Adjudication Committees are expected to evaluate efficacy of ProTmune in the study, one through assessing acute GvHD and the other through assessing CMV tissue-invasive disease, viremia and additional clinical outcomes.

According to the Center for International Blood and Marrow Transplant Research, there are approximately 30,000 allogeneic HCT procedures performed globally each year, of which approximately 65% utilize mPB as the donor cell source. 35-50% of HCT patients develop acute GvHD, and 70-80% of HCT patients experience at least one severe infection.

About ProTmune
ProTmune is a programmed cellular immunotherapy that is undergoing clinical development for use as an allogeneic hematopoietic cell source for HCT. The cell therapy is produced by modulating mobilized peripheral blood (mPB) with two small molecules to enhance the biological properties and therapeutic function of immune cells. Preclinical data for ProTmune were presented at the American Society of Hematology 2015 Annual Meeting, demonstrating that the T-cell compartment of mPB is functionally less allo-reactive. Notably, these data indicate a decrease in both the expression of costimulatory receptors and the production of pro-inflammatory cytokines, and an increase in the production of anti-inflammatory cytokines such as IL-10. Additionally, a single administration of programmed mPB cells showed a statistically-significant reduction in GvHD score and improvement in survival, as compared to vehicle-treated cells, in preclinical models of allogeneic HCT. Importantly, Fate Therapeutics has also demonstrated that the cancer-fighting properties of programmed immune cells are preserved following adoptive transfer in preclinical models.

About Fate Therapeutics, Inc.
Fate Therapeutics is a biopharmaceutical company dedicated to the development of programmed cellular immunotherapeutics for cancer and immune disorders. The Company's cell-based product pipeline is comprised of off-the-shelf immuno-oncology therapeutics, including NK- and T-cell-based candidates derived from induced pluripotent cells, and

immuno-regulatory therapeutics, including hematopoietic cell-based candidates for protecting the immune system of patients undergoing hematopoietic cell transplantation and for suppressing auto-reactive T cells of patients with auto-immune disorders. Its adoptive cell therapy candidates 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 timing of the Company's initiation of, and expected clinical trial design for, its clinical investigation of ProTmune, and the potential ability of ProTmune to prevent, or reduce the incidence of, acute GvHD and severe viral infections. 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 Form 10-Q for the quarter ended September 30, 2015, and from time to time 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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