September 26, 2016

Fate Therapeutics Receives FDA Orphan Drug Designation for ProTmune™ in Allogeneic Hematopoietic Cell Transplantation

SAN DIEGO, Sept. 26, 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 Orphan Drug Designation for ProTmune™, the Company's lead product candidate that is currently undergoing Phase 1/2 clinical investigation. The FDA designation is for "prevention of graft-versus-host disease in patients undergoing allogeneic hematopoietic cell transplantation" and broadly covers diseases, including blood cancers and genetic disorders, for which the procedure is performed.

"The granting of both orphan drug and Fast Track designations for ProTmune validates the product candidate's unique therapeutic potential to address life-threatening complications and improve the curative potential of allogeneic HCT," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "Graft-versus-host disease is a significant cause of morbidity and mortality in patients undergoing allogeneic HCT and there are no FDA-approved therapies to prevent its occurrence. Through our development of ProTmune, we seek to transform the allogeneic HCT paradigm by providing immunocompromised patients a therapeutically-optimized donor graft containing immune cells with reduced alloreactivity and enhanced infection-fighting and anti-tumor properties."

Graft-versus-host disease (GvHD) is a severe immunological complication that arises when newly-transplanted donor immune cells attack the patient's tissues and organs, resulting in a potentially fatal immune system reaction. Despite the use of protocols to prevent its occurrence, up to 50 percent of patients experience GvHD. Additionally, GvHD is treated systemically with immunosuppressive agents, with only about half of patients responding to treatment. The systemic use of these agents increases a patient's risk of severe infection from bacteria, viruses and fungi as well as cancer relapse, further compromising the curative potential of allogeneic HCT.

The FDA provides orphan designation to drugs and biologics which are intended for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders that affect fewer than 200,000 people in the United States. Orphan drug designation would provide seven years of market exclusivity in the United States, with certain exceptions, if market approval is granted for ProTmune. Orphan designation also qualifies a company for various development incentives, including tax credits for qualified clinical testing and a waiver of PDUFA filing fees.

About ProTmune™
ProTmune™ is an investigational programmed cellular immunotherapy undergoing clinical development for the prevention of acute GvHD and cytomegalovirus (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 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 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, severe infections, including cytomegalovirus infection, and disease relapse. 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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