

Fate Therapeutics Announces Preclinical Data from Immuno-Regulatory CD34+ Cell Therapy for Autoimmune Diseases

One-time Administration of Programmed Cells Demonstrates Durable Disease Correction in Type 1 Diabetes Mouse Model

ToleraCyte[™] Product Candidate Exhibits Enhanced Trafficking to the Pancreas and Potent Regulation of Autoreactive T Cells in Preclinical Testing

Preclinical Data Package to be Presented at American Diabetes Association's 76th Scientific Sessions

SAN DIEGO, June 11, 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 it will present preclinical data for ToleraCyte[™], its programmed CD34⁺ immuno-regulatory cell

product candidate for autoimmune diseases, at the American Diabetes Association's 76th Scientific Sessions being held June 10-14 in New Orleans, Louisiana. Scientists from Fate Therapeutics and Boston Children's Hospital demonstrated that a single administration of programmed cells results in durable correction of type 1 diabetes in a well-established non-obese diabetic (NOD) mouse model. In addition, the group showed that a single administration of programmed cells significantly delays the onset of type 1 diabetes in NOD mice. Fate Therapeutics is advancing ToleraCyte through late-stage preclinical development under a collaboration with Boston Children's Hospital led by Paolo Fiorina, M.D., Ph.D., Assistant Professor of Pediatrics at Boston Children's Hospital and Harvard Medical School.

"The use of a programmed CD34⁺ cell therapy is an intriguing new therapeutic approach with disease-modifying potential for patients with type 1 diabetes, and the preclinical data suggest that CD34⁺ cells may play a critical role in treating autoimmunity," said Michael J. Haller, M.D., an associate professor of pediatric endocrinology at University of Florida and an active investigator in Type 1 Diabetes TrialNet clinical studies. "These data are especially interesting given we have recently

shown in a clinical study conducted at the University of Florida that treating patients with G-CSF, a CD34⁺ cell mobilizing agent, in combination with a mild conditioning regimen, preserved beta cell function in patients with established type 1 diabetes."

The scientific team at Fate Therapeutics and Boston Children's Hospital explored the disease-modifying potential of ToleraCyte in humanized and mouse models of type 1 diabetes. In *in vivo* studies using hyperglycemic NOD mice designed to mimic new-onset type 1 diabetes, a one-time administration of programmed cells resulted in the durable correction of disease, as compared to vehicle-treated cells. Additionally, in pre-hyperglycemic NOD mice, a one-time administration of programmed cells demonstrated a statistically-significant delay in the onset of disease, where the median time to onset was not reached by Day 140 as compared to untreated mice (median time to onset = Day 115; p=0.0004). Finally, in a

humanized model of type 1 diabetes, programmed CD34⁺ cells showed enhanced trafficking to the pancreas and regulation of T-cell activation. Together, these preclinical results support the premise that ToleraCyte may serve as a disease-modifying immunotherapy for patients with type 1 diabetes.

"We believe ToleraCyte holds unique potential to immunologically check autoreactive T cells that are directly responsible for the destruction of healthy tissue in certain autoimmune and inflammatory disorders," said Dan Shoemaker, Ph.D., Chief

Scientific Officer of Fate Therapeutics. "Our programmed CD34⁺ cells exhibit enhanced trafficking and possess potent immuno-regulatory capabilities, expressing powerful T-cell regulatory factors including PD-L1 and IDO1."

The Company's poster presentation entitled "*Using Pharmacologically Programmed CD34*⁺ Cells for the Treatment of Type 1 Diabetes" will be held on Sunday, June 12, 2016 at the American Diabetes Association's 76th Scientific Sessions from 12:00 — 2:00 p.m. CT. The presentation will be available for review on the Publications section of the Company's website at <u>www.fatetherapeutics.com/publications</u> following its conclusion.

About ToleraCyte

ToleraCyte is a programmed CD34⁺ cell immunotherapy that is undergoing preclinical investigation for the treatment of autoimmune and inflammatory disorders. The immuno-regulatory cell therapy is comprised of CD34⁺ cells that have been programmed *ex vivo* with a proprietary combination of pharmacologic modulators. ToleraCyte is designed to optimize the

capacity of CD34⁺ cells to effectively traffic to sites of inflammation and express potent T-cell regulatory factors, including PD-L1 and IDO1.

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 <u>www.fatetherapeutics.com</u>.

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 Company's advancement of, and the anticipated timing, progress, milestones and plans related to, the Company's adoptive immunotherapy programs. 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 that results observed in prior studies, including preclinical studies of ToleraCyte and programmed hematopoietic cells, will not be observed in ongoing or future studies involving these product candidates, the risk that the Company may cease or delay preclinical or clinical development activities for any of its existing or future product candidates for a variety of reasons (including requirements that may be imposed by regulatory authorities and requirements for regulatory approval, difficulties or delays in patient enrollment in current and planned clinical trials, and any adverse events or other negative results that may be observed during preclinical or clinical development), the risk that the Company's research and development collaborations may not be successful or may be terminated, and the risk that product candidates may not provide the anticipated therapeutic benefits. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our 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 the Company's other investor communications. Fate Therapeutics 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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