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Fate Therapeutics Announces FDA Clearance of Investigational New Drug Application for FATE-NK100 Natural Killer Cell Cancer Immunotherapy

SAN DIEGO, March 13, 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 that the U.S. Food and Drug Administration (FDA) has cleared an investigational new drug application for FATE-NK100, the Company's first-in-class adaptive memory natural killer (NK) cell product candidate. The Company expects a first-in-human clinical trial of FATE-NK100 for advanced acute myeloid leukemia (AML) to open enrollment at the Masonic Cancer Center, University of Minnesota following approval of the Center's institutional review board.

"AML patients who relapse or are refractory to front-line therapy have very poor prognoses and very few treatment options, and we have shown that natural killer cell immunotherapy is a safe and efficacious approach to target and durably destroy leukemia cells in these patients," said Sarah Cooley, M.D., Associate Professor of Medicine, Division of Hematology, Oncology and Transplantation at the University of Minnesota and the clinical trial's lead investigator. "FATE-NK100 is a next-generation immunotherapy that is uniquely tailored to fully realize the anti-cancer activity of natural killer cells, and we are excited to pioneer the clinical investigation of this novel NK cell therapy."

FATE-NK100 is comprised of adaptive memory NK cells, a highly specialized and functionally distinct subset of natural killer cells expressing the memory-like activating receptor NKG2C and the maturation marker CD57. Adaptive memory NK cells have been clinically shown to have potent and persistent effector function in patients with AML.

"FATE-NK100 is a first-in-class NK cell product candidate designed to enhance direct tumor cell killing, resist immune checkpoints and promote endogenous T-cell anti-tumor response," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We look forward to exploiting the multifaceted effector function of these adaptive memory NK cells across liquid and solid tumors, both as a monotherapy and in combination with therapeutic antibodies."

Unlike T cells that require specific tumor antigen recognition to elicit an effective immune response, natural killer cells selectively identify and destroy cancer cells through recognition of a repertoire of stress signals commonly expressed across tumor cell types, while leaving normal healthy cells unharmed. Additionally, while T-cell immunotherapy most commonly requires a patient-specific treatment approach, natural killer cells sourced from healthy donors have been safely administered to patients for over a decade without causing graft-versus-host disease or triggering significant side effects, such as cytokine release syndrome.

The first-in-human study will evaluate the safety and determine the maximum dose of a single intravenous infusion of FATE-NK100 in subjects with refractory or relapsed AML. Secondary and investigational endpoints will assess anti-tumor activity including rates of complete response, clearance of minimal residual disease, disease-free survival and overall survival. The clinical trial will utilize an accelerated dose escalation design, which is intended to test up to four dose levels of FATE-NK100 with one subject enrolled per dose level until a dose-limiting toxicity (DLT) is observed. The study will convert to a 3+3 design in the event a DLT is observed, and will enroll a ten subject expansion cohort at the maximum dose level.

FATE-NK100 has demonstrated in preclinical studies enhanced anti-tumor activity across a broad range of liquid and solid tumors, improved persistence and increased resistance to immune checkpoint pathways compared to NK cell therapies that are being clinically administered today. Additionally, FATE-NK100 has been shown in preclinical models to significantly augment antibody-directed cellular cytotoxicity against cancer cells when administered in combination with a monoclonal antibody, including antibodies that target CD20, HER2 and EGFR antigens. FATE-NK100 is produced through a feeder-free, seven-day manufacturing process during which natural killer cells sourced from a healthy donor are activated *ex vivo* with pharmacologic modulators, inducing the robust formation of adaptive memory NK cells.

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.

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 safety and therapeutic potential of NK cells including FATE-NK100, the timing of the initiation of, and expected clinical trial design for, the clinical investigation of FATE-NK100, and the potential of FATE-NK100 to treat patients with AML and other cancers. 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 FATE-NK100 may not be replicated in subsequent studies or clinical trials, and the risk that FATE-NK100 may not produce therapeutic benefits or may cause other unanticipated adverse effects. 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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