May 10, 2017

Fate Therapeutics Announces FDA Clearance of Investigational New Drug Application for FATE-NK100 in Advanced Solid Tumors

SAN DIEGO, May 10, 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 authorized the Company's investigational new drug (IND) application for FATE-NK100 in advanced solid tumors. The Company plans to promptly initiate the DIMENSION study, an open-label, multi-center, accelerated dose-escalation clinical trial of FATE-NK100 as a monotherapy and in combination with monoclonal antibody therapy in subjects who have failed approved therapies.

"The FDA's clearance of this IND is a significant milestone, ushering in the opportunity to develop a powerful new immunologic approach to solid tumors that bridges innate and adaptive immunity. Activated NK cells can intrinsically seek out and directly kill transformed cancer cells, including antibody-coated tumor cells, and can trigger a long-lived adaptive T-cell immune response through pro-inflammatory cytokine release," said Chris Storgard, M.D., Chief Medical Officer of Fate Therapeutics. "We are excited to begin this clinical investigation of FATE-NK100, which has demonstrated in preclinical studies the potential to selectively eliminate tumor cells while leaving normal healthy cells unharmed."

The Company plans to enroll subjects in the DIMENSION study across three FATE-NK100 treatment arms in an outpatient setting: as monotherapy for solid tumor malignancies, including small cell lung cancer and hepatocellular carcinoma; in combination with trastuzumab for advanced HER2+ cancers, including breast and gastric cancers; and in combination with cetuximab for advanced EGFR1+ cancers, including colorectal and head and neck cancers. Activation of a patient's NK cells has been clinically proven to play a major role in the anti-tumor efficacy of many monoclonal antibodies, including trastuzumab and cetuximab.

In preclinical models, FATE-NK100 has been shown 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. Additionally, FATE-NK100 has displayed enhanced anti-tumor activity across a broad range of hematologic and solid tumors, improved persistence and increased resistance to immune checkpoint pathways in preclinical studies compared to NK cell therapies that are being clinically administered today.

The primary objective of the DIMENSION study is to evaluate the safety and determine the maximum tolerated dose of a single intravenous infusion of FATE-NK100. Other objectives include determination of objective response rate, time-to-tumor progression, progression-free survival and overall survival.

Each of the three arms of the DIMENSION study will enroll in parallel utilizing accelerated dose-escalation, with each arm expected to include an expansion cohort of up to an additional twenty subjects at the maximum tolerated dose level. In addition, observation of a RECIST partial response or greater will enable additional expansion of up to ten subjects in that tumor type.

About FATE-NK100

FATE-NK100 is a first-in-class natural killer (NK) cell cancer immunotherapy comprised of adaptive memory NK cells, a highly specialized and functionally distinct subset of activated NK cells expressing the memory-like activating receptor NKG2C and the maturation marker CD57. FATE-NK100 is produced through a feeder-free, seven-day manufacturing process during which NK cells sourced from a healthy donor are activated *ex vivo* with pharmacologic modulators. An investigator-initiated clinical trial of FATE-NK100 is currently being conducted at the Masonic Cancer Center, University of Minnesota for the treatment of refractory or relapsed acute myelogenous leukemia.

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, our clinical development plans for FATE-NK100, including the timing of, and our ability to conduct, clinical studies, and the potential of FATE-NK100 to treat patients with cancer, including advanced solid tumors, as a monotherapy and in combination with monoclonal antibody therapy. 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 or other ongoing clinical studies of FATE-NK100 may not be replicated in current or 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.

Contact:
Christina Tartaglia
Stern Investor Relations, Inc.
212.362.1200
christina@sternir.com