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Fate Therapeutics Announces Initial Clinical Data from Ongoing First-in-Human VOYAGE Study of FATE-NK100 for Relapsed / Refractory Acute Myelogenous Leukemia at SITC 2017 Annual Meeting

Subject in Dose Cohort 2 Achieves Morphologic Leukemia-free State at Day 14

No Dose Limiting Toxicities Reported

SAN DIEGO, Nov. 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 initial clinical data from the ongoing VOYAGE Phase 1 study of FATE-NK100 as a monotherapy for the treatment of refractory or relapsed acute myelogenous leukemia (AML). The data were presented today in a poster session at the Society for Immunotherapy of Cancer (SITC) 2017 Annual Meeting in National Harbor, Maryland.

Anti-leukemia activity was observed with FATE-NK100, the Company's first-in-class adaptive memory natural killer (NK) cell cancer immunotherapy, in each of the treated dose cohorts of the VOYAGE study. The subject in the second dose cohort ($2x10^7$ cells/kg) achieved a morphologic leukemia-free state (mLFS) following a single intravenous infusion of FATE-NK100 as a monotherapy. Prior to treatment, the subject presented in relapse, was refractory to conventional NK cell therapy and had 50% leukemic blasts in the bone marrow. At Day 14 following treatment, a bone marrow biopsy showed clearance of leukemic blasts in the marrow, and approximately $3x10^4$ FATE-NK100 cells per mL were measured in the peripheral blood.

"These are encouraging early data for FATE-NK100 in refractory and relapsed AML, especially in patients with such high leukemic blast burden in the marrow that have exhausted all therapeutic options," 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. "The disappearance of all cells with morphologic characteristics of leukemia validates the *in vivo* anti-leukemia activity of FATE-NK100. We look forward to continuing enrollment in the VOYAGE study and to dosing the first patient with FATE-NK100 in the APOLLO study for the treatment of women with recurrent ovarian cancer."

The subject in the first dose cohort of VOYAGE ($1x10^7$ cells/kg) presented in primary induction failure with 87% leukemic blasts in the bone marrow. Two weeks following a single infusion of FATE-NK100, a bone marrow biopsy revealed a nearly 50% reduction in leukemic blasts. In addition, approximately 76% of NK cells in the peripheral blood were of FATE-NK100 origin.

"The significant reduction of leukemic blasts in the bone marrow observed in both subjects without any dose-limiting toxicities is very promising," stated Scott Wolchko, Chief Executive Officer of Fate Therapeutics. "Although the second subject's morphologic leukemia-free state was not sustained following a single dose of FATE-NK100, the clearance of leukemia at Day 14 coupled with the presence of FATE-NK100 in circulation validates the cell product's enhanced potency and persistence. We look forward to continuing subject enrollment and to combining FATE-NK100 with monoclonal antibody therapy for the treatment of advanced solid tumors through the launch of our DIMENSION study."

The accelerated dose-escalation design of VOYAGE is designed to evaluate the safety and determine the maximum dose of a single intravenous infusion of FATE-NK100 as a monotherapy. The three dose levels are $1x10^7$, $2x10^7$ and up to $1x10^8$ adjusted to kg of body weight. FATE-NK100 has now advanced through the first two dose cohorts with no reports of dose limiting toxicities (DLTs). The third dose cohort is currently enrolling. A ten-subject expansion cohort is expected to be enrolled at the maximum dose level.

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 maturation marker CD57. Higher frequencies of $CD57^+$ NK cells in the peripheral blood or tumor microenvironment in cancer patients have been linked to better clinical outcomes. In preclinical studies, FATE-NK100 has demonstrated enhanced anti-tumor activity across a broad range of hematologic and solid tumors, with augmented cytokine production, improved persistence and increased resistance to immune checkpoint pathways compared to other NK cell therapies that are being clinically administered today.

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.

About VOYAGE
VOYAGE is an open-label, accelerated dose-escalation, Phase 1 clinical trial designed to evaluate the safety and determine the maximum dose of a single intravenous infusion of FATE-NK100 as a monotherapy administered after lymphodepleting chemotherapy followed by sub-cutaneous IL-2 administration in subjects with refractory or relapsed acute myelogenous leukemia (AML). One subject is being enrolled in each of the three planned dose cohorts. A ten-subject expansion cohort is expected to be enrolled at the maximum dose level. Anti-tumor activity of FATE-NK100 is being assessed by rates of complete response, disease-free survival and overall survival. The study is being conducted at the Masonic Cancer Center, University of Minnesota as an investigator-initiated study.

Acute Myelogenous Leukemia
Acute myelogenous leukemia (AML) is an aggressive cancer of the blood and bone marrow that progresses rapidly without treatment. Cancerous cells called leukemic blasts multiply and displace normal cells in the bone marrow, disrupting normal blood cell production. Each year in the United States, about 19,900 people are diagnosed with AML, and about 10,400 people die from all forms of the disease, according to the American Cancer Society. Current treatment options for AML consist of reducing and eliminating cancer cells mainly through chemotherapy, radiation therapy, and stem cell transplantation.

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 expected clinical development plans for 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 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 and current clinical trials of FATE-NK100 may not be replicated in current or future 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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