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Fate Therapeutics Announces Publication of Preclinical Data in Cancer Research and FDA Clearance of Third IND for FATE-NK100

Non-Clinical Studies Demonstrate Unique Anti-tumor Activity of Natural Killer Cell Product Candidate

FDA Clears IND for FATE-NK100 in Ovarian Cancer

SAN DIEGO, Aug. 08, 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 the peer-reviewed publication of non-clinical data describing the unique properties and anti-tumor activity of FATE-NK100, the Company's first-in-class adaptive memory natural killer (NK) cell product candidate. Additionally, the Company announced that the U.S. Food and Drug Administration (FDA) has cleared a third investigational new drug (IND) application for FATE-NK100, with the most recent clearance authorizing the study of FATE-NK100 in women with ovarian cancer resistant to, or recurrent on, platinum-based treatment.

The findings published online by *Cancer Research* (doi:10.1158/0008-5472.CAN-17-0799), a peer-reviewed journal of the American Association of Cancer Research, are the first demonstration of a GMP-compatible manufacturing process that induces both NK cell expansion and acquisition of CD57, a marker of NK cell maturation. Higher frequencies of $CD57^+$ NK cells in the peripheral blood or tumor microenvironment in cancer patients have been linked to better clinical outcomes. FATE-NK100 is comprised of adaptive memory NK cells expressing CD57 and the memory-like activating receptor NKG2C.

"Our ability to successfully and reproducibly manufacture FATE-NK100 enables, for the first time, the administration of therapeutic quantities of mature, highly cytotoxic NK cells to patients for the treatment of cancer. Multiple studies point to a distinct role for $CD57^+$ NK cells in cancer immune-surveillance, where the acquisition of CD57 on NK cells is associated with a profound shift towards enhanced effector function and potency," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We look forward to initiating a third clinical trial of FATE-NK100 in advanced malignancies, and are excited to see early clinical results from each of these studies in the coming months."

The published data show that FATE-NK100 exhibits greater natural cytotoxicity and antibody-dependent cellular cytotoxicity against a variety of solid tumor cell lines and markedly increases cytokine production in response to target cell recognition. Additionally, in a xenogeneic model of ovarian cancer, the data show that FATE-NK100 exhibits better and more consistent anti-tumor efficacy.

The clinical trial in ovarian cancer cleared for conduct by the FDA is expected to evaluate the safety and determine the maximum dose of a single infusion of FATE-NK100 when administered intraperitoneally in the outpatient setting. An accelerated dose escalation design is intended to test up to three dose levels of FATE-NK100 with one subject enrolled per dose level. If a dose-limiting toxicity (DLT) is observed, the study will convert to a 3+3 design. A ten subject expansion cohort is planned at the maximum dose level. Other endpoints include objective response rate at 28 days post-infusion and of progression-free and overall survival at six months post-infusion.

The Masonic Cancer Center, University of Minnesota is currently conducting an investigator-initiated clinical trial of FATE-NK100 for the treatment of refractory or relapsed acute myelogenous leukemia. In addition, in May 2017, the FDA authorized an IND application for the clinical investigation of FATE-NK100 in combination with monoclonal antibody therapy in subjects with advanced solid tumors who have failed approved therapies.

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 and the memory-like activating receptor NKG2C. 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 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 initiate and conduct, clinical studies, and the potential of FATE-NK100 to treat patients with cancer, including acute myelogenous leukemia and 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.

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