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Fate Therapeutics Announces First Subject Treated with FATE-NK100 in APOLLO Study for Recurrent Ovarian Cancer

SAN DIEGO, Dec. 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 that the first subject has been treated in the APOLLO study of FATE-NK100 in women with ovarian cancer resistant to, or recurrent on, platinum-based treatment. The clinical trial is intended to evaluate the safety and determine the maximum dose of FATE-NK100, the Company's first-in-class, donor-derived adaptive memory natural killer (NK) cell cancer therapy, as a monotherapy when administered intraperitoneally in the outpatient setting. A clinical assessment of patients with ovarian cancer has previously shown that endogenous NK cells within the peritoneal fluid exhibit an altered phenotype with reduced cytolytic function.

"Women today often are treated with intraperitoneal chemotherapy, and the administration of FATE-NK100 directly within the peritoneal cavity is an exciting therapeutic strategy to restore NK cell function, promote persistence and inhibit tumor growth," said Melissa A. Geller, M.D., Associate Professor in the Department of Obstetrics, Gynecology and Women's Health, Division of Gynecologic Oncology at the University of Minnesota and the lead investigator of the clinical trial at the Masonic Cancer Center. "Ovarian cancer is a disease of middle age women, and over 60% of women with ovarian cancer initially present with advanced disease. For these women, the rate of recurrence is around 70%, and there is an urgent need for novel therapeutic strategies since standard treatments in the recurrent setting provide dismal response rates especially in platinum resistant disease."

The APOLLO study is an open-label, accelerated dose-escalation, Phase 1 clinical trial of FATE-NK100 in subjects with recurrent ovarian, fallopian tube or primary peritoneal cancer. Up to three dose levels of FATE-NK100 are intended to be assessed to evaluate safety and determine the maximum dose. Other endpoints to be evaluated include objective response rate at 28 days, and progression-free and overall survival at six months. Subjects with stable disease or better at Day 28 following infusion may be considered for retreatment with FATE-NK100.

Ovarian cancer is the fifth leading cause of cancer-related death among women, and is the deadliest of gynecologic cancers. The American Cancer Society estimates that in 2017, about 22,440 new cases of ovarian cancer will be diagnosed and 14,080 women will die of ovarian cancer in the United States. While a high proportion of women respond to initial platinum-based chemotherapy, around 70% of patients diagnosed with ovarian cancer will have a recurrence. While recurrent ovarian cancer is treatable, it is rarely curable and there is a significant need for more effective, better-tolerated therapies.

About FATE-NK100
FATE-NK100 is a first-in-class, donor-derived 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 APOLLO
APOLLO is an open-label, accelerated dose-escalation, Phase 1 clinical trial in subjects with recurrent ovarian, fallopian tube or primary peritoneal cancer designed to evaluate the safety and determine the maximum dose of a single infusion of FATE-NK100 as a monotherapy when administered via intraperitoneal catheter after out-patient chemotherapy followed by sub-cutaneous IL-2 administration. Up to three dose levels of FATE-NK100 are intended to be assessed (1x107 cells/kg, >1x107 cells/kg to ≤3x107 cells/kg, and up to 1x108 cells/kg). In the event a dose limiting toxicity is observed, the clinical trial will convert to a 3+3 design. A ten-subject expansion cohort is expected to be enrolled at the maximum dose level. Other endpoints include objective response rate at 28 days, and progression-free and overall survival at six months, post-infusion of FATE-NK100. The clinical trial is being conducted at the Masonic Cancer Center, University of Minnesota as an investigator-initiated study.

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 recurrent ovarian, fallopian tube or primary peritoneal cancer. 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.

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