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Fate Therapeutics and Regents of the University of Minnesota Expand Research Collaboration for Clinical Translation of Engineered iPSC-Derived Natural Killer Cell Cancer Immunotherapy

Off-the-Shelf Natural Killer Cell Therapy Being Developed to Complement Standard-of-Care Monoclonal Antibody Treatment for Cancer

First-of-Kind Product Candidate to be Manufactured from an Engineered Induced Pluripotent Stem Cell Line

Intellectual Property Covering Compositions of Novel CD16 and Chimeric Antigen Receptors Exclusively Licensed

SAN DIEGO, Feb. 27, 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 an expansion of its research collaboration with the Regents of the University of Minnesota (UMN) to initiate the clinical translation of a first-of-kind product candidate, an off-the-shelf targeted natural killer (NK) cell cancer immunotherapy derived from an engineered induced pluripotent stem cell (iPSC) line.

The Company plans to produce the product candidate from a single iPSC that is first genetically engineered to express a high-affinity, non-cleavable CD16 (hnCD16) receptor and then is clonally-expanded to generate a master engineered pluripotent cell line. Similar to master cell lines used for the manufacture of therapeutic antibodies, a master engineered pluripotent cell line can be used to repeatedly create clonal populations of effector cells to enable off-the-shelf treatment of many thousands of patients. Preclinical production runs have shown that a single iPSC can yield a homogeneous population of over one million iPSC-derived NK (iNK) cells.

"Using induced pluripotent stem cells, which possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body, is a first-of-kind approach that enables tremendous product development optionality for the Company. Our first announced iPSC-derived cell product candidate, a natural killer cell incorporating CD16 as the targeting element, is derived from a master pluripotent cell line. This line serves as the backbone into which we have engineered other targeting and functional elements, such as chimeric antigen receptors, and from which we can derive effector cells including NK and T cells," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "We look forward to working closely with the FDA and regulatory authorities in other territories in 2017 to advance our revolutionary approach for off-the-shelf cellular immunotherapy into clinical development."

NK cells have been proven to play a major role in cancer immunotherapy including antibody-dependent cellular cytotoxicity (ADCC), which involves targeting of tumor cells by monoclonal antibodies for the treatment of breast, head and neck, colorectal and certain blood cancers. Activation of NK cells through CD16, a receptor that can bind to antibody-coated tumor cells, unleashes potent NK cell-mediated anti-tumor responses including direct lysis of target cells and cytokine secretion for adaptive immune cell recruitment. The Company's hnCD16 receptor, which is licensed exclusively from UMN, incorporates two unique modifications designed to enhance the anti-tumor activity of NK cells. The receptor has been modified to augment its binding affinity to certain monoclonal antibodies, and also to prevent its shedding from the surface of NK cells upon activation which can otherwise diminish effector function.

In preclinical studies, the Company has shown that its hnCD16-iNK cell product candidate exhibits potent and persistent anti-tumor activity *in vitro* and *in vivo* in multiple tumor cell recognition and killing assays:

- hnCD16-iNK cells exhibit superior ADCC when combined with cetuximab, as compared to conventional NK cells sourced from peripheral blood and cord blood, in an *in vitro* killing assay of a human ovarian cancer cell line that is positive for EGFR expression;
- hnCD16-iNK cells show a dose-dependent killing response in combination with rituximab *in vitro* in a $CD20^+$ human lymphoblast-derived B-lymphocyte cell line killing assay; and
- hnCD16-iNK cells augment anti-tumor activity in combination with trastuzumab *in vivo*, as compared to mice treated with trastuzumab alone, in a $HER2^+$ ovarian cancer model, where the anti-tumor effect at Week 6 of hnCD16-iNK plus trastuzumab was durable with no tumor detectable by imaging in 80% of the mice as compared to trastuzumab alone where all mice displayed tumor burden.

The collaboration is being led by renowned NK cell biologist Jeffrey S. Miller, M.D., Deputy Director of the Masonic Cancer Center, University of Minnesota. The Company has exclusively licensed from UMN foundational intellectual property covering compositions of a modified CD16 as well as certain chimeric antigen receptors and of immune cells expressing such receptors, and also maintains an option to exclusively license all intellectual property arising from research and development activities under the collaboration.

In addition to its collaboration with UMN, Fate Therapeutics has also partnered with Memorial Sloan Kettering Cancer Center for the development of off-the-shelf T-cell product candidates using engineered iPSCs. Research and development activities are being led by Michel Sadelain, M.D., Ph.D., Director of the Center for Cell Engineering and the Stephen and Barbara Friedman Chair at Memorial Sloan Kettering Cancer Center.

About Fate Therapeutics, Inc.
Fate Therapeutics is a 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 impact, benefits, timing, and conduct of the partnership between the Company and UMN, as well as the capabilities, expertise, and responsibilities of each, and the therapeutic potential of any cellular immunotherapies developed under the partnership. 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, risks associated with the success, cost, and timing of research and product development activities under the collaboration, the risk of cessation or delay of any development activities under the collaboration for a variety of reasons, including any inability to develop or manufacture off-the-shelf NK cell products, and the risk that any off-the-shelf NK cell therapies developed under the collaboration may not be suitable for therapeutic applications and may not provide the anticipated therapeutic benefits. 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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