

Fate Therapeutics Announces Generation of CAR-targeted, TCR-null CD8 α β ⁺ T Cells from Clonal Engineered Master Pluripotent Cell Line for Off-the-Shelf T-cell Immunotherapy

One-time Engineering Event Using iPSCs and CRISPR/Cas9 Yields Genetically Modified, Self-Renewing Clonal Master Pluripotent Cell Line

Master Pluripotent Cell Line Engineered with Complete Elimination of TCR Expression and CAR Insertion into TRAC Locus used as Renewable Cell Source for CD8 α β ⁺ CAR T-Cell Generation

Clonally-derived CAR T Cells Display TRAC-regulated CAR Expression, Antigen Specificity and Anti-tumor Potency

IND-enabling Activities for First-in-Human Clinical Trial of FT819 Initiated

SAN DIEGO, Dec. 09, 2017 (GLOBE NEWSWIRE) -- Fate Therapeutics, Inc. (NASDAQ:FATE), a biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders, announced today the generation of chimeric antigen receptor (CAR)-targeted CD8 α β ⁺ T cells from a clonal engineered master pluripotent cell line (MPCL). The clonal engineered MPCL was created from an induced pluripotent stem cell (iPSC), which was modified in a one-time engineering event using CRISPR/Cas9 to both insert a CAR into the T-cell receptor α constant (TRAC) locus and eliminate T-cell receptor (TCR) expression. The groundbreaking development enables the renewable production of CAR-targeted, TCR-null CD8 α β ⁺ T cells that are not restricted to an individual patient for off-the-shelf administration.

The breakthrough was reported today at the 59th American Society of Hematology Annual Meeting and Exposition by scientists from the laboratories of Michel Sadelain, M.D., Ph.D., Director, Center for Cell Engineering, Memorial Sloan Kettering Cancer Center and Fate Therapeutics. In September 2016, Fate Therapeutics and Memorial Sloan Kettering Cancer Center launched a multi-year partnership led by Dr. Sadelain to develop off-the-shelf T-cell product candidates using clonal engineered MPCLs. The collaborators are currently conducting preclinical studies and finalizing current good manufacturing practice protocols for the development of CAR-targeted, TCR-null T-cell immunotherapies. A first-in-human clinical trial of FT819, a CAR19 T-cell product candidate derived from a clonal engineered MPCL with complete elimination of TCR expression and TRAC-regulated CAR expression, is being planned.

"The use of a clonal engineered master pluripotent cell line enables cost-effective manufacture, timely availability and reliable off-the-shelf delivery of targeted T-cell cancer immunotherapy without patient restriction," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "Additionally, unlike conventional allogeneic CAR T-cell approaches that involve billions of heterogeneous engineering events to modify the genomic function of primary T cells, an engineered iPSC clone is defined by a single uniform engineering event. As a result, a T-cell product generated from a clonal engineered master pluripotent cell line is homogeneous with respect to genomic modification and cell product composition. This revolutionary approach has the potential to mediate safer, more effective pharmacologic activity, including in combination with cycles of other cancer treatments."

In February 2017, Dr. Sadelain and colleagues published a set of preclinical studies in the journal *Nature* using primary T cells demonstrating that directing a CD19-specific CAR to the TRAC locus with CRISPR/Cas9 resulted in uniform CAR expression and enhanced T-cell potency as compared to conventional CAR T cells. Scientists from the laboratories of Sadelain and Fate Therapeutics advanced the observation by instead engineering iPSCs and generating CD8 α β ⁺ T cells from a clonal engineered MPCL with a CD19-targeted CAR inserted into the TRAC locus and complete elimination of TCR expression. The collaborators demonstrated that the CAR-targeted, TCR-null CD8 α β ⁺ T cells display antigen-specific anti-tumor potency, including cytokine release and targeted cellular cytotoxicity.

Fate Therapeutics has built an extensive intellectual property portfolio broadly covering the genomic engineering of iPSCs and off-the-shelf engineered T- and NK cell cancer immunotherapies. Its proprietary portfolio includes compositions and methods for editing iPSCs to modify their biological properties using CRISPR and other nucleases, including the use of CRISPR to insert a CAR in the TRAC locus for endogenous transcriptional control, and for manufacturing cells of all hematopoietic lineages from iPSCs including T cells. In addition, the Company has an exclusive license from Memorial Sloan

Kettering covering iPSC-derived T cells expressing chimeric antigen receptors for human therapeutic use, and maintains an option to exclusively license intellectual property arising from all research and development activities under the collaboration.

About Fate Therapeutics' iPSC Product Platform

The Company's proprietary induced pluripotent stem cell (iPSC) product platform enables large-scale generation of off-the-shelf, engineered, homogeneous cell products that can be administered in repeat doses to mediate more effective pharmacologic activity. Human iPSCs possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. The Company's first-of-kind approach involves engineering human iPSCs in a one-time genetic modification event, and selecting a single iPSC for maintenance as a clonal master pluripotent cell line (MPCL). Similar to master cell lines used for the manufacture of monoclonal antibodies, clonal MPCLs can serve as a renewable cell source for the consistent and repeated manufacture of homogeneous cell products with the potential to treat many different diseases and many thousands of patients in an off-the-shelf manner. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 90 issued patents and 100 pending patent applications.

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 impact, benefits, timing, and conduct of research and development activities of the Company, including under a partnership between the Company and Memorial Sloan Kettering Cancer Center, as well as the capabilities, expertise, and responsibilities of each, either alone or under the partnership, and the therapeutic potential of any cellular immunotherapies developed by the Company, including 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 T-cell products, and the risk that any off-the-shelf T-cell products developed, including under the partnership, 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.

Contact:

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