IND enabling development of FT516: A Natural Killer Cell Immunotherapy for Cancer Derived from a Human Inducible Pluripotent Stem Cell

Grant Award Details

IND enabling development of FT516: A Natural Killer Cell Immunotherapy for Cancer Derived from a Human Inducible Pluripotent Stem Cell

Grant Type: Late Stage Preclinical Projects

Grant Number: CLIN1-10893

Project Objective: File IND and achieve full readiness to initiate Phase 1 clinical trial in development of FT516: A Natural Killer Cell Immunotherapy for Cancer Derived from a Human Inducible Pluripotent Stem Cell

Investigator:

Name:	Bob Valamehr
Institution:	Fate Therapeutics, Inc.
Type:	PI

Disease Focus: Cancer, Solid Tumors

Human Stem Cell Use: iPS Cell

Cell Line Generation: iPS Cell

Award Value: $4,000,000

Status: Closed

Progress Reports

Reporting Period: Final Operational Milestone #4

View Report

Grant Application Details

Application Title: IND enabling development of FT516: A Natural Killer Cell Immunotherapy for Cancer Derived from a Human Inducible Pluripotent Stem Cell

Public Abstract:

Therapeutic Candidate or Device

FT516: A Natural Killer Cell Immunotherapy for Cancer Derived from a Human Inducible Pluripotent Stem Cell Line

Indication

FT516 monotherapy for patients with advanced cancer and in combination with approved ADCC-competent monoclonal antibodies

Therapeutic Mechanism

FT516 drug product is comprised of natural killer (NK) cells derived from a clonal human induced pluripotent stem cell (iPSC) master cell line that has been genetically modified to express a high-affinity variant of immunoglobulin FcgammaRIIIa (CD16a) receptor and to prevent cleavage by the metalloprotease ADAM17. Both modifications enhance NK cell targeting and elimination of cancerous cells by release of cytolytic granules, cytokine activation, and antibody-dependent cellular cytotoxicity.

Unmet Medical Need

FT516 is designed to exhibit innate anticancer activity and to synergise with therapeutic monoclonal antibodies to significantly improve outcomes for patients with progressive cancer and few other effective therapeutic options

Project Objective

Full readiness to initiate Phase 1 clinical trial

Major Proposed Activities

- Complete manufacturing process control and release assay development. Complete engineering-, process-qualification and clinical manufacturing runs
- Completion of IND-enabling preclinical studies, investigational new drug application preparation and submission
- Complete clinical trial database construction and clinical site identification and study initiation

Statement of Benefit to California:

Citizens of the State of California will benefit by development of an effective treatment option for patients suffering from a variety of cancers. More than 50,000* Californians die of cancer each year, including ~6000* patients who fail current treatment options for colorectal cancer, and ~4000* who succumb to effects of breast cancer: Last year of life Medicare costs for these patients exceeds $70,000^ per patient. (Sources -^www.chcf.org, *California Cancer Facts and Figures 2017)

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