

First-ever US clinical trial of engineered iPSC-derived cell therapy for blood cancer

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A new cancer clinical trial has opened at the M Health Fairview University of Minnesota Medical Center that leverages the groundbreaking research on stem cells and natural killer (NK) cells done



at the Masonic Cancer Center and applies it to attack acute myeloid leukemia (AML) and B-cell lymphoma. The first-of-its-kind NK cell cancer immunotherapy, called FT516, is manufactured from a human induced pluripotent stem cell (iPSC) that has been genetically engineered to enhance its anti-tumor activity.

The first-in-human clinical trial of FT516, sponsored by Fate Therapeutics, will be run locally by Claudio Brunstein, MD, Ph.D., who is a professor of Medicine at the U of M Medical School, a member of the Masonic Cancer Center, and the medical director of the Adult Blood and Marrow Transplant and Cellular Therapy Program at M Health Fairview.

"We potentially have an unlimited source of very similar, reproducible cancer fighters," said Brunstein. "This is opening a whole new door in cellular therapy. With increased modifications to these NK cells, we can elevate their ability to attack tumors. As we add more functionality to NK cells, we have the potential to bring together multiple anti-tumor mechanisms and more effectively target and kill cancer."

FT516 is the first in a new generation of cell-based cancer immunotherapies. The cell product originates from a single genetically engineered iPSC, which serves as a clonal master cell line that can be repeatedly used to mass-produce large quantities of cells in a cost-effective manner.

"FT516 is the first-ever cell therapy derived from a genetically engineered iPSC cleared for clinical testing in the world," said Scott Wolchko, president and CEO of Fate Therapeutics. "Our use of a master engineered iPSC line uniquely supports a new treatment paradigm, where engineered cell products are available off-the-shelf and multiple doses can be readily administered to a patient, with the goal of driving deeper and more durable responses."



FT516 was produced and manufactured at the U of M's Molecular and Cellular Therapeutics (MCT) center, which offers full-service development and manufacturing of cell- and tissue-based products, monoclonal antibodies and other therapeutic proteins, as well as active pharmaceutical ingredients for use in Phase I, II or III clinical trials. M Health Fairview, the clinical partner of the Masonic Cancer Center, supports the MCT in the production of these molecules.

Provided by University of Minnesota Medical School

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