Methods and Compositions Comprising Fusion Proteins for the Identification of Immunotherapy Cells (CAR-T)

Lead Investigators

William J. Kelly, PhD, Professor, Chemical Engineering, Director, Nova Cell Center, Villanova University

Scott Dessain, MD, PhD, Professor and Joseph and Ray Gordon Chair in Clinical Oncology and Research, Lankenau Institute for Medical Research

Background and Unmet Need

Chimeric Antigen Receptor T-cell therapy or CAR-T is a type of cancer immunotherapy that utilizes a patient's own T cells that are genetically modified to recognize and attack cancer cells. This form of treatment has become massively popular as a customized solution to cancer therapies. While a new therapeutic area, the CAR-T market has been valued at $12.88 billion in 2025 and is expected to grow to $128.55 billion at a compound annual growth rate of 29.1%.[1]

There currently is no scalable, easy-to-use approach for isolating more efficacious CAR+ phenotypes. No selection of preferred phenotypes occurs in current manufacturing, despite one serious and problematic side effect for CAR-T and CAR-T products (CRS) being caused by over-secretion of cytokines and some level of cytokine secretion being linked to higher efficacy for cell therapies such as CAR-T and CAR-NK.

Accordingly, the identification and isolation of these cells are of vitally important to the efficacy of these custom treatments. Improved methodology for identification and isolation is needed to identify and select immunotherapy cells with the particular characteristics required for successful CAR-T therapy. Further, novel tools are needed to enable for the characterization of immunotherapy cells to allow for the single-cell cytokine secretion analysis and subsequent identification and isolation for therapeutic treatment.

Opportunity

The Kelly lab has invented novel fusion proteins for the identification and selection of immunotherapy cells. These proteins enable the user to specifically identify cells with specific immunotherapeutic characteristics and subsequent isolation of specific cytokine-secreting cell populations.

These novel fusion proteins comprise components that recognize both immunotherapy cells and cytokines released by such cells, including CAR cells that include but not limited to tumor antigens or biomarkers such as CD19. The use of the fusion protein enables the analysis of single-cell cytokine secretion and subsequent identification and isolation of specific TNF-alpha secreting cell population which are important for this cell therapy to be effective.

These proteins produce a defined/desired level of a secreted molecule, i.e., a cytokine such as IFN-gamma. Specific cytokines enhance or suppress immune function depending on various circumstances. Isolated cells produce specific cytokines that can positively affect immune function and improve the capability of T cells (CAR-T) to produce anti-tumor effects while separating those that may have suppressor function that is an important future component of

[1] *CAR T-Cell Therapy Market Size Worth USD 128.55 Billion by 2024.,* Biospace, July 2025.

Continued on back

CAR-T immunotherapy. When the novel fusion proteins are linked to the appropriate particle, they can be in theory used in one step, to isolate cells that both 1) express an important surface protein (i.e., the CAR protein); and 2) are over or under producing an important cytokine (i.e., IFN- gamma or TNF-alpha). Such a processing step would eliminate CAR- cells that have no efficacy as well as cells that do not secrete the desired level (high or low) of an important cytokine (i.e., IFN-gamma).

Unique Attributes

- Rapid identification and isolation of targeted cells.
- Fusion proteins can, in theory, bind simultaneously bind to an important surface protein, i.e., the CAR protein, and a secreted cytokine from the same cell such as IFN- gamma or TNF-alpha.

Applications

Immediate application in the development and manufacturing of CAR-T therapies.

Stage of Development

Experimental Proof of Concept

Intellectual Property

US Patent Application published February 2024, US 2024/0060043 A1

Licensing and Collaboration Opportunity

Villanova University is seeking a licensee or collaborators to commercialize the invention.

INSTITUTIONAL CONTACT

Amanda M. Grannas, PhD
VP & Chief Research Officer
+1 610.519.4881
Email

L2C PARTNERS CONTACT

Merle Gilmore, MBA
+1 610.662.0940
Email

Alex Toglia, MS
+1 610.937.1067
Email