A fully human EGFRvIII-targeted bispecific antibody engaging T cells for antitumor therapy

Value Proposition

The most common malignant brain tumor, glioblastoma multiforme (GBM), remains uniformly fatal despite surgery, radiation, and chemotherapy. Conventional therapy for malignant glioma fails to specifically target tumor cells. In contrast, substantial evidence indicates that if appropriately redirected, T cells can precisely eradicate tumors. Current therapy for malignant glioma is incapacitating as a result of nonspecific, dose-limiting toxicity. In contrast, immunotherapy promises an exquisitely precise approach, and evidence now exists that adoptively transferred T cells expressing modified T-cell receptors (TCR) or chimeric antigen receptors (CAR) can eradicate large tumors in the central nervous system (CNS) in both preclinical and clinical studies. Although promising, these approaches rely on ex vivo expanded and genetically manipulated T cells, processes that are laborious, inconsistent, and often require complex viral transductions. In addition, these T cells are almost always targeted to antigens shared with normal tissues, which has led to lethal autoimmune toxicity.

Technology

Duke inventors have developed a clinically translatable method to specifically target malignant glioma using a tumor-specific, fully human bispecific antibody that redirects patients' own T cells to recognize and destroy tumors. This translatable, off-the-shelf, fully human therapeutic is produced in a fashion compatible with existing clinical antibody manufacturing infrastructure and has significant potential to improve public health and quality of life for patients affected by malignant glioma and other cancers. The inventors have demonstrated robust, antitumor immune responses capable of curing well-established, patient-derived malignant glioma that heterogeneously expresses the target antigen. Investigators are approaching the start of a phase 1 study at this point.

Advantages

- A fully human, EGFRvIII:CD3-targeted bispecific antibody suitable for clinical translation supported by a grant providing $5 M in antibody optimization and manufacturing through to a phase 1 study
- A therapeutic approach that has significant potential to enhance the standard of care for patients of glioblastoma multiforme (GBM)
Fully optimized cell lines ready for manufacturing on a clinical scale

**Publications**

- A Rationally Designed Fully Human EGFRvIII:CD3-Targeted Bispecific Antibody Redirects Human T Cells to Treat Patient-derived Intracerebral Malignant Glioma (Clinical Cancer Research, 2018)

**Patents**

- Patent Number: 10,053,514
  Title: CERTAIN IMPROVED HUMAN BISPECIFIC EGFRvIII ANTIBODY ENGAGING MOLECULES
  Country: United States of America

- Patent Number: 10,053,514
  Title: CERTAIN IMPROVED HUMAN BISPECIFIC EGFRvIII ANTIBODY ENGAGING MOLECULES
  Country: United States of America

- Patent Number: 20144287244
  Title: CERTAIN IMPROVED HUMAN BISPECIFIC EGFRvIII ANTIBODY ENGAGING MOLECULES
  Country: Australia

- Patent Number: 20144287244
  Title: CERTAIN IMPROVED HUMAN BISPECIFIC EGFRvIII ANTIBODY ENGAGING MOLECULES
  Country: Australia

- Patent Number: 2,917,919
  Title: CERTAIN IMPROVED HUMAN BISPECIFIC EGFRvIII ANTIBODY ENGAGING MOLECULES
  Country: Canada

- Patent Number: 2,917,919
  Title: CERTAIN IMPROVED HUMAN BISPECIFIC EGFRvIII ANTIBODY ENGAGING MOLECULES
  Country: Canada

- Patent Number: 6242484
  Title: CERTAIN IMPROVED HUMAN BISPECIFIC EGFRvIII

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