

THERAPEUTIC AND PROPHYLACTIC ANTI-INFLUENZA VIRUS NEURAMINIDASE 1 (N1) ANTIBODY (CD6) WITH A NOVEL EPITOPE THAT SPANS NEURAMINIDASE (NA) DIMERS

Technology Summary

Influenza virus neuraminidase (NA) protein is a surface protein that plays an essential role in virus replication. Drugs and antibodies that block NA function can reduce both the symptoms and the length of illness. However, variants of influenza virus are resistant to NA inhibitors. The neuraminidase 1 (N1) subtype of NA is important because it is found in the two pandemic H1N1 influenza virus strains (1918 Spanish flu and 2009 swine flu) and the H5N1 avian influenza virus.

CD6 is a potent monoclonal antibody against N1 subtypes of NA that inhibits the enzymatic activity of the NA protein, including NA variants resistant to NA inhibitors. Anti-neuraminidase antibody CD6 is a novel antibody that spans a conserved 30 amino acid epitope across the lateral face of a NA dimer. The CD6 anti-NA antibody CD6 may offer an alternative to therapeutic NA inhibitors currently available. In a murine model of infection, a single dose of antibody was protective against lethal challenge with H1N1 influenza virus. The CD6 antibody can be used in combination with other therapeutic agents or antibodies in an “cocktail”. Additionally, this unique anti-NA antibody may be useful in combination with known neutralizing anti-hemagglutinin (HA) antibodies.

Potential Commercial Applications

- Prophylactic and therapeutic against influenza virus infections
- Diagnostic tests for influenza virus infections
- Reagent to measure the potency of H1N1 NA in influenza virus vaccines

Competitive Advantages

- Monoclonal antibody demonstrated to be effective against circulating H1N1 influenza viruses
- Monoclonal antibody binds a novel, conserved epitope spanning NA dimers
- Monoclonal antibody is well-suited for an antibody cocktail that includes anti-HA antibodies.

Development Stage: *in vitro* data; *in vivo* data

Inventors: Hongquan Wan (FDA); Maryna Eichelberger (FDA); Hua Yang (CDC); James Stevens (CDC); David Shore (CDC); and Rebecca Garten (CDC)

Publications:

“Structural characterization of a protective epitope spanning A(H1N1)pdm09 influenza virus neuraminidase monomers.” *Nat Commun.* 2015 Feb 10; 6: 6114. PMID: [25668439](https://pubmed.ncbi.nlm.nih.gov/25668439/)

Intellectual Property:

United States patent: US [10,072,070](https://www.uspto.gov/patents/publications/10072070) B2, issued 09.11.2018

Product Area: Therapeutic antibody; research tools; diagnostic assays; vaccine development

FDA Reference No: E-2015-001

Licensing Contact:

Bill Ronnenberg, MS, JD/MIP
FDA Technology Transfer Program
Email: FDAlnventionlicensing@fda.hhs.gov
Phone: 240-402-4561