ANTI-INFLUENZA A NEURAMINIDASE (NA) MONOCLONAL ANTIBODIES

Technology Summary

Anti-influenza A neuraminidase (NA) antibodies may be useful for diagnostic tests, research, quality control, and vaccine development. The antibodies may be useful for identifying antigens or epitopes specific for a NA subtype of a virus responsible for influenza infection and for validating the conformation of antigenic proteins.

Multiple anti-neuraminidase (NA) monoclonal antibodies are available to license, including antibodies for NA subtypes N1, N2, and N9. These monoclonal antibodies were produced using influenza viruses that include A/Anhui/1/2013 (N9), A/Victoria/361/2012 (N2), A/California/07/2009 (N1), and A/Brisbane/59/2007 (N1). The antibodies are characterized for specificity, epitope binding, and cross reactivity to other influenza viruses. In particular, the monoclonal antibody designated as CD6 binds a novel epitope spanning two NA monomers, protects mice from lethal H1N1 infection, and is broadly reactive. Additional antibodies for other NA subtypes may be available upon request.

Potential Commercial Applications

- A diagnostic test to detect influenza virus subtypes
- Immunoassays
- Vaccine development and manufacture
- Potential therapeutic use to treat influenza A infection

Competitive Advantages

- Antibodies are categorized based on specificity, epitope binding, and neutralizing capability
- CD6 demonstrated protective immunity in a lethal challenge mouse study with the homologous and heterologous N1-containing viruses

Development Stage: Monoclonal antibodies, hybridoma cell lines, and *in vitro* characterization data are available

Inventors: Hongquan Wan (FDA) et al.

Publications:

"Molecular basis for broad neuraminidase immunity: conserved epitopes in seasonal and pandemic H1Nq as well as H5N1 influenza viruses/" *J. Virol*. 2013 Aug; 87(16) 9290-300. PMID: 23785204

"Structural characterization of a protective epitope spanning A(H1N1)pdm09 influenza virus neuraminidase monomers." *Nat Commun.* 2015 Feb 10; 6: 6114. PMID: 25668439

"Comparative Efficacy of the Monoclonal Antibodies That Bind to Different Epitopes of the 2009 Pandemic H1N1 Influenza Virus Neuraminidase." *J. Virol.* 2015 Oct 14; (90)1: 117-28. PMID: 26468531

"Assessment of influenza A neuraminidase (subtype N1) potency by ELISA." *J. Virol. Methods.* 2017 Jun; 244: 23-28. PMID: 28257802

"Comparison of the Efficacy of N9 Neuraminidase-Specific Monoclonal Antibodies against Influenza A(H7N9) Virus Infection." *J. Virol.* 2018 Jan 30; (92)(4). PMID: 29167344

"Antigenic Drift of the Influenza A(H1N1)pdm09 Virus Neuraminidase Results in Reduced Effectiveness of A/California/7/2009 (H1N1pdm09)-Specific Antibodies." *MBio*. 2019 Apr 9; 10(2). PMID: 30967460

Product Area: Research tools; diagnostic assays; vaccine development

FDA Reference No: E-2015-001 (N1), E-2013-008 (N1), E-2019-012 (N2, N9)

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