

THERAPEUTIC HEPATITIS C VIRUS ANTIBODIES

Technology Summary

Therapeutic antibodies against Hepatitis C Virus (HCV) have not been very effective in the past and there is evidence that this may result in part from interfering antibodies generated during infection that block the action of neutralizing antibodies. These neutralizing antibodies prevent HCV infection of a host cell.

FDA researchers developed monoclonal antibodies against HCV that can neutralize different genotypes of HCV. In particular, two antibodies were identified that bind to the envelope (E2) protein of HCV found on the surface of the virus. One of the monoclonal antibodies neutralizes HCV genotype 1a, the most prevalent HCV strain in the U.S., infection and in vitro data show that it is not blocked by interfering antibodies. The second antibody binds a conserved region of E2 and can cross neutralize a number of genotypes including genotypes 1a and 2a. These monoclonal antibodies have the potential to be developed either alone or in combination into therapeutic antibodies that prevent or treat HCV infection. These antibodies may be used for preventing HCV re-infection in HCV patients who undergo liver transplants; a population of patients that is especially vulnerable to the side effects of current treatments for HCV infection

Potential Commercial Applications

- Therapeutic antibodies for the prevention and/or treatment of HCV infection.

Competitive Advantages

- Therapeutic antibodies with potentially fewer side effects than current treatments for HCV infection.
- Potential to be developed into an alternative treatment for HCV infected liver transplant patients, who often cannot tolerate the side effects of current drug treatments.

Development Stage: *in vitro* studies

Inventors: Stephen Feinstone, Hongying Duan, Marian Major, Pei Zhang, Alla Kachko

Publications:

“New neutralizing antibody epitopes in hepatitis C virus envelope glycoproteins are revealed by dissecting peptide recognition profiles.” *Vaccine* 2011 Dec 9;30(1):69-77 PMID [22041300](#)

“Amino acid residue-specific neutralization and non-neutralization of hepatitis C virus by monoclonal antibodies to the E2 protein.” *J. Virol.* 2012 Dec; 86(23): 12686-94 PMID: [22973024](#)

Intellectual Property:

United States patent: US [9,399,672](#) B2, issued 07.26.2016

Product Area: Biologics

FDA Reference No: E-2012-002

Licensing Contact:

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