Statin Treatments for Viral Diseases

(VA Reference No. 07-018)

Novel method for treatment of patients with hepatitis C virus by using statins either alone or in combination with current standard therapy

Technology
Treatment of chronic hepatitis C with statins

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Key Features
- Proven to be safe for use in HCV patients
- Designed to increase anti-HCV effects and result in higher cure rates
- Potential to delay or prevent HCV drug resistance
- High concentrations of statins in the liver could lead to reduced dosing of current therapy and a potential reduction in side effects

Stage of Development
Reduced to practice with successful demonstration in vitro and clinical studies

Field
Therapeutic
- Anti-viral
- Statin
- Hepatitis C

Patent Status
US Patent Filed 11/973,189

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Technology
The Department of Veterans Affairs has developed a method for the use of statins alone or in combination with pegylated interferon and ribavirin for the treatment of hepatitis C (HCV) and other viral diseases.

Description
The invention is the use of statins, drugs that are commonly used to lower high cholesterol, may significantly benefit the current treatments for both HBV and HCV. The combination of antivirals and statins has been shown to decrease hepatitis C virus (HCV) and hepatitis B virus (HBV) replication in vivo, improve sustained viral remission and improve liver disease when used as a monotherapy. This data is the basis of a phase II randomized-control trial adding fluvastatin (FLV) to standard-of-care treatment for HCV, which has been enrolling patients since 2008.

The trial study concluded that FLV is safe for use in patients chronically infected with HCV. The effects of FLV as a monotherapy are modest, variable, and short lived. These findings, along with the aforementioned retrospective analysis and the *in vitro* study suggesting synergism with alpha-interferon, support pilot trials combining FLV with standard pegylated interferon plus ribavirin (PI+R) therapy.

Publications:
- Bader, T, Madhoun, M, Rizvi, S, et al. Statins improve ALT values in chronic hepatitis C patients with abnormal values. *Gastroenterology* 2007; 132(Suppl 2): A603;2013.
- Bader, T., Fazili, J., Madhoun, M., Aston, C., Hughes, D., Seres, K., and Hasan, M. Fluvastatin Inhibits Hepatitis C Replication in Humans. *The American Journal of Gastroenterology* (2008) 103, 1383–1389;

Competitive Advantage
The standard therapy of infected patients with pegylated interferon and ribavirin is only mildly effective and is associated with serious side effects. There is an urgent need for more selective, potent and better-tolerated therapies for chronic hepatitis C.

This invention:
- Has the potential to increase the anti-HCV effects and result in a higher cure rate.
- Has the potential to delay or prevent HCV resistance that arises from current therapy due to the ability of HCV to quickly develop resistance mutations for compounds targeting viral enzymes.

Status
The Department of Veterans Affairs is looking for a partner for further development and commercialization of this technology through a license and the VA inventors are available to collaborate with interested companies through a Cooperative Research and Development Agreement (CRADA).