

Hepatoprotective effect of alpha 1 anti trypsin (Hadasit)

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Need:

Protection of liver function and physiology during the course of a range of acute or chronic liver diseases, which include viral, bacterial, parasitic, immune-mediated, fatty liver, metabolic syndrome, diabetes, and atherosclerosis. A liver-supportive therapy as adjunct to other more specific therapies where available is a significant medical need given the shortfall in efficacy offered by most current liver-directed therapeutics. All causes of hepatitis alone have an economic impact of \$10Bs-100B per year. Thus, a new therapeutic for alleviating symptoms of multiple types of hepatitis and other liver-related diseases like NASH that can be used in combination with other therapeutics may be expected to have a market potential in \$Bs based on pharmaco-economic considerations alone.

Innovation:

The anti inflammatory effect of alpha 1 anti trypsin is well described. We propose a novel use of alpha 1 anti trypsin as a hepatoprotector for the treatment of liver disorders.

Findings:

The effect of AAT was tested in two liver disease models and found to be hepatoprotective.

Following induction of hepatitis in the ConA model, AAT administration alleviates liver damage as manifest by decreases in serum ALT and AST levels and in leukocyte infiltration into the liver. Likewise in the acetaminophen toxicity model, AAT administration results in decreased serum AST levels. These effects are well-accepted markers of alleviating symptoms of hepatitis.

Competitive advantage:

AAT is an FDA-approved plasma-derived generic product for replacement therapy and augmentation, with a recombinant product in development. The use of approved AAT for liver disorders opens new and attractive markets for this product, with the advantage that only liver-directed clinical trials need to be conducted and not the technical and manufacturing development of the drug itself.

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