Therapeutic Hepatitis C Virus Vaccine

Status: OPEN TO ACCRUAL

Eligibility Criteria

Age: 18 years to 60 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Documentation of chronic hepatitis C infection based on serum positivity for HCV RNA for at least 6 months interval. HCV genotype will be recorded. All genotypes will be eligible. 2. Patients who are not under DAA treatment. 3. Liver fibrosis (by Metavir stage F1 or F0) within one year of the screening visit, documenting extent of liver disease consistent with chronic hepatitis C with evidence of inflammation and/or fibrosis. Fibrosis scaling is based on an ultrasound based elastography (FibroScan, Echosen, Paris France) with cutoff of 7.5 kPa or liver biopsy. 4. Screening laboratory values within institutional normal range, with the exception of liver enzymes ? 3 ULN and bilirubin <1.5 ULN, or judged to be not clinically significant by clinical investigator. 5. Ability and willingness of subject to give written informed consent. 6. Negative pregnancy test on the day prior to each vaccination. 7. Willingness to use adequate contraception by study participants. Subjects must agree not to participate in a conception process (e.g., active attempts to become pregnant or to impregnate, sperm donation, or in vitro fertilization), and if participating in sexual activity that could lead to pregnancy, subjects must use a form of contraception as listed below while on study vaccine and for 60 days after stopping study vaccine. Women without reproductive potential (i.e., have reached menopause or undergone hysterectomy, bilateral oophorectomy, or tubal ligation) or women whose male partner has undergone successful vasectomy with documented azoospermia or has documented azoospermia for any other reason, are eligible without requiring the use of contraception.

Exclusion Criteria:

1. History of decompensated liver disease, including but not restricted to, portal hypertension as manifested by a known history of gastroesophageal varices, variceal bleeding, ascites or encephalopathy, histopathologic or clinical evidence of cirrhosis, hepatocellular carcinoma, or renal impairment consistent with hepatorenal syndrome; history of significant other non-HCV chronic liver disease, i.e. alcoholic hepatitis, autoimmune hepatitis. 2. History of hematologic disease (e.g., cryoglobulinemia, lymphoma), renal disease, dermatologic disease (e.g., lichen planus, porphyria cutanea tarda). 3. Seropositive for hepatitis B surface antigen (HBsAg) or HIV-1 antibody. 4. Autoimmune diseases or clinically serious cardiac, pulmonary, gastrointestinal, hepatic, renal or neurologic disease, which in the opinion of the investigator will compromise ability to participate in the study. 5. Previous receipt of any HCV experimental vaccine. 6. Pregnancy and breast-feeding. 7. Prior or current systemic cancer chemotherapy. 8. Investigational agents and immunomodulators (cyclosporine, hematological growth factors, systemic corticosteroids, interleukins or interferons) within 90 days prior to study entry. NOTE: Subjects may not be on antiretroviral agents not yet approved by the FDA as part of a clinical trial or expanded access program. 9. Anaphylaxis or allergy to vaccine components. 10. Active drug or alcohol use or dependence that, in the opinion of the investigator, would interfere with adherence to study requirements. 11. Any other serious diseases other than HCV infection including current or recent (within 5 years) cancers. 12. Liver fibrosis with Metavir stage F2 or above. 13. Subjects with diabetes mellitus, who are at higher risk for more rapid progression of fibrosis. 14. Subjects who are immunocompromised or immunosuppressed due to disease or medications. 15. Subjects with any laboratory abnormalities Grade 3 or greater. 16. Women who are lactating.

Conditions & Interventions

Interventions:
Biological: HCVax, drug: Hcvax?
Conditions:
Chronic Hepatitis C Infection, Infectious and Parasitic Diseases (001-139)
Keywords:
Therapeutic HCV vaccine, HCV

More Information

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Phase: I
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