

First vaccine for viral hepatitis C could become a reality

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Berlin, Germany, Friday 01 April 2011: Early data from phase I trials of an HCV vaccine presented today at the International Liver CongressTM show encouraging results, with high immunogenicity and good safety profile.^{1,2}

In the first study1, a therapeutic T-cell vaccine, based on novel adenoviral vectors was used on a small population of treatment naive patients with chronic genotype 1 HCV infection. Intra-muscular vaccination was administered 2 or 14 weeks into a 48-week course of treatment with Peg-IFNa2a/ribavirin. 50% of vaccinated patients had CD4+ and CD8+ HCV specific T-cell responses as detected by ELISpot at 2-8 weeks post boost, showing a strong immunogenicity for the vaccine. Local and systemic adverse events to vaccination were mild, with no evidence of liver immunopathology (measured by liver transaminase levels).

The second study2 looked at the potential for a prophylactic vaccine based on similar novel adenoviral vectors technology (replicativedefective human Ad6 and a novel simian AdCh3 vector that encode 1985 amino-acids derived from the NS3-5 region of a genotype-1b strain). 27 healthy volunteers were vaccinated following a double prime, heterologous boost strategy. The <u>vaccine</u> induced polyfunctional CD4+ and CD8+ T cells responses which were maintained up to 52 weeks post prime. Overall vaccination was very well tolerated with mild/moderate local and systemic reactions and no serious adverse advents.



Professor Heiner Wedemeyer, EASL's Secretary General commented: "Vaccines are an exciting area of research now with the potential to add to the range of treatments available for patients with chronic <u>viral</u> <u>hepatitis</u>. These are early data but results are very encouraging indeed and as experts, we look forward to more scientific evidence being made available to support this new technology as a future treatment option as well as potentially preventing infection."

Previous research and data presented at the International Liver Congress shows that vaccination with adenoviral vectors induced highly potent and durable T-cell responses in healthy human and that similar vectors may prevent chronic infection in animals.³ This is the first time the immunogenicity and safety of vaccination was tested on HCV patients and healthy subjects.

More information: References

1. Kelly C et al. A therapeutic vaccine for HCV based on novel, rare, adenoviral vectors. Abstract presented at the International Liver CongressTM 2011. <u>www1.easl.eu/easl2011/program/Orals/329.htm</u>

2. Barnes E. Phase I trials of a highly immunogenic and durable T-cell vaccine for Hepatitis C virus based on novel, rare, adenoviral vectors. Abstract presented at the International Liver CongressTM 2011. www1.easl.eu/easl2011/program/...ers/Abstract1018.htm

3. Folgori A et al. A T-cell HCV vaccine eliciting effective immunity against heterologous virus challenge in chimpanzees. Nature Medicine - 12, 190 - 197 (2006)

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