



HuMax-HepC™

A Fully Human Therapeutic Monoclonal Antibody targeting the E2 Envelope Protein of the Hepatitis C Virus (HCV)

Primary therapeutic application as anti-infective agent in HCV-positive liver transplant patients.

NONCONFIDENTIAL BROCHURE 17 October 2008

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Summary

- HCV infection is the most common indication for liver transplantation in Western Europe and North America.
- Monoclonal antibodies specific for HCV may be effective as an immunoprophylactic in preventing post-transplant HCV reinfection.
- HuMax-HepC was isolated from a patient chronically infected with HCV genotype 4 and recognizes a conformational epitope of HCV-E2.
- HuMax-HepC potently neutralizes binding of HCV-E2 to HCV-susceptible cells.
- Cross-reactivity of HuMax-HepC against HCV-E2 of all major HCV genotypes has been demonstrated.
- . • In a mouse model, HuMax-HepC protects against *in vivo* high titer HCV challenge with infectious serum containing a mixture of HCV patient isolates.
 - All mice (6/6) treated with HuMax-HepC showed complete protection against infection. Only one mouse (1/6) treated with HuMax-HepC showed a low HCV RNA titer (17,773 IU/ml) on day 8 after HCV challenge. This was rapidly resolved and titer was undetectable on the second, third and fourth week of observation.
 - In contrast, 5 of the 6 mice that were treated with an isotype control antibody showed robust and sustained HCV infection, as indicated by HCV serum viral loads ranging from 3267 to 480,000 IU/ml.

In conclusion, HuMax-HepC is a promising candidate for the development of immunoprophylaxis against HCV infection.