VectorLogics

NOVEL THERAPEUTIC VACCINE AGENTS FOR VIRAL LIVER DISEASES AND LIVER CANCER

IBDV (VLI-03A & VLI-03B) FACTS SHEET AT A GLANCE

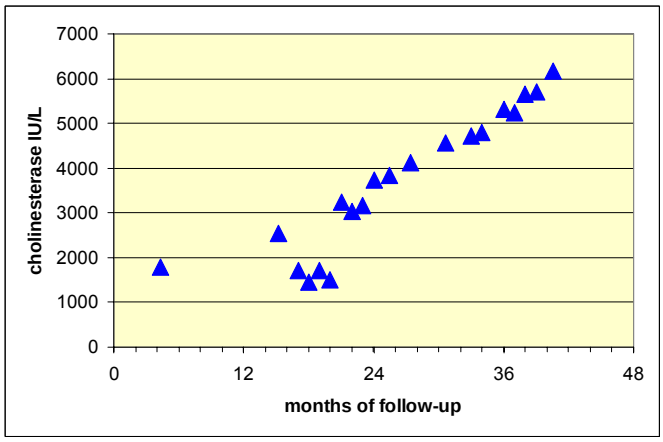
- Breakthrough product concept for treating viral liver diseases and liver cancer
- Compelling safety and efficacy data from a proof-of-principle clinical trial
- Clinical response data on cirrhotic patients with life threatening complications
- Potential for fast-track development for advanced viral hepatitis and liver cancer patients
- Extensive intellectual property
- Significant commercial opportunity

Product Profile

VectorLogics (VLI) is developing two therapeutic vaccine product candidates utilizing an attenuated IBDV avian virus that causes no disease in humans. The first product candidate (VLI-03A) is a proprietary recombinant IBDV vector with proven safety and anti-HBV/HCV activity that is being developed as a novel orally-administered therapeutic vaccine to treat advanced chronic HCV infections. The second product candidate (VLI-03B) is comprised of a recombinant IBDV vector engineered to deliver and express interferon alpha (IFN-α) in the liver for the local treatment of recurrent liver cancer (hepatocellular carcinoma; HCC). These two related products provide application to distinct and complementary markets.

Superinfection Therapy

The superinfection therapeutic vaccine strategy is an innovative technological platform that exploits viral competition for the treatment of persistent viral infections. The clinical observation that infection by one type of hepatitis virus (e.g. HCV) was often abolished following accidental superinfection by a second hepatitis virus (e.g. HBV) prompted the idea of intentional superinfection therapy. A preliminary proof-of-principle clinical trial conducted in Hungary demonstrated that superinfection with a *non*-pathogenic IBDV shortened the duration of the clinical symptoms in 42 acute hepatitis patients. In addition, fewer patients progressed into chronic disease.



Cholinesterase activity levels indicating regeneration of the liver in a chronic HCV patient treated with IBDV

Therapeutic Hepatitis Vaccine

HCV infection is a causative agent of chronic liver disease with worldwide prevalence of 170 million cases. Options are few, if sustained viral clearance cannot be achieved by conventional treatment. Unfortunately, conventional therapies become progressively less effective if chronic hepatitis evolves into cirrhosis. Once cirrhosis develops, treatment is aimed at the management of complications. Challenging the current assumption that such patients are untreatable, IBDV superinfection stabilized and/or improved the life threatening complications of cirrhotic patients. The treatment remained effective during long-term administration without toxicity and

IBDV Superinfection Therapy Advantages

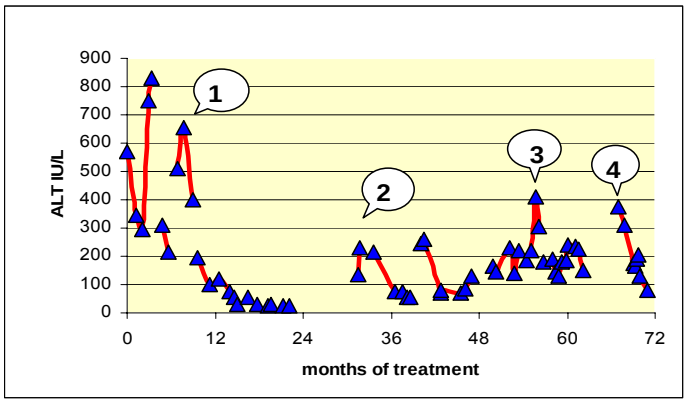
IBDV Superinfection therapy offers several advantages:

- Proven anti-HBV/HCV activity
- Highly stable biological agent that can be orally administered
- Does not generate drug-resistance
- Can be used repeatedly over a long period
- It has no systemic toxicity
- Adapted to grow in mammalian cells for commercial manufacturing

Additional advantages for the treatment of advanced liver cancer:

- Induces liver regeneration
- Sustained local delivery of therapeutic proteins
- Systemic toxicity of interferon can be reduced

was associated with the regeneration of the cirrhotic liver. VLI is developing orally-administered recombinant therapeutic hepatitis vaccines based on an attenuated avian virus that causes no disease in humans. The first product will capitalize on the absence of effective treatment for cirrhotic hepatitis.



The marker of liver injury (ALT) declined after INF treatment (1). After the patient became resistant to INF, three superinfection therapy courses (2, 3, 4) repeatedly improved liver function.

VLI is in the process of designing a comprehensive program of preclinical and clinical activity to progress this interesting product opportunity. This will include the design of Phase II and pivotal clinical trials to develop and test the IBDV superinfection therapy in advanced hepatitis patients who exhausted conventional treatments. Consequently, this product is unique and has the potential to result in the development of a new class of drugs.

Hepatocellular Carcinoma

HCC is one of the most prevalent and lethal liver cancers worldwide resulting in more than 600,000 global deaths per year. Following curative resection of HCC, up to 90% of postoperative death is due to recurrent disease, which is chemo-resistant. Any therapy that can prevent a new HCC from developing in the remnant liver, will improve the results of liver resection. Potential benefits of interferon (IFN) in preventing recurrence after HCC resection have been suggested by three randomized clinical trials. INF therapy is however fraught with serious dose-dependent toxicity. The main risk factor of HCC is cirrhosis of the liver which results from chronic HBV and HCV infections. Therefore, an IBDV vector having anti-HBV/HCV and potentiating liver regeneration activity is an ideal starting point for a recombinant vector designed to reduce INF treatment associated systemic toxicity. VLI is developing a novel genetically engineered IBDV based vector to deliver and express IFN-α locally in the liver. This novel drug candidate can be administered long-term without systemic toxicity, thus providing supplementary treatment of advanced HCC for people with no other options available at present.

Proprietary Position

VectorLogics licensed rights for the IBDV technology and related treatment of viral hepatitis from HepC Ltd., Hungary. VectorLogics has established a broad portfolio of intellectual property pertaining to vector delivery and relevant technologies based on its extensive internal research and licensing activities.

Summary

VectorLogics' hepatitis program provides a unique approach for the treatment of advanced chronic HCV infections. A proof-of-principle clinical trial demonstrated in acute hepatitis patients that superinfection with a non-pathogenic IBDV resulted in a faster resolution of clinical symptoms and fewer patients progressed into chronic disease. Importantly, several chronic hepatitis patients with life threatening conditions were stabilized with clinical improvement. The liver cancer program is directed towards the recurrence of malignancy after surgery of advanced cancer patients with very few options available.

References

American Cancer Society, Cancer Facts & Figures, 2009.
Pyenson B, et al., (2009) Consequences of Hepatitis C Virus (HCV): Costs of a Baby Boomer Epidemic of Liver Disease. http://www.milliman.com/expertise/healthcare/publications/rr/consequences-hepatits-c-virus-RR05-15-09.php
Malekzadeh R, et al., (2004) Reversibility of cirrhosis in chronic hepatitis B. Clin Gastroenterol Hepatol April;2(4):344-7.
Bakács T, Mehrishi JN. (2004) Examination of the value of treatment of decompensated viral hepatitis patients by intentionally coinfecting them with an apathogenic IBDV and using the lessons learnt to seriously consider treating patients infected with HIV using the apathogenic hepatitis G virus. Vaccine 23(1), 3-13.
Csatary LK, et al., (1999) Successful treatment of decompensated chronic viral hepatitis by bursal disease virus vaccine. Anticancer Res.19(1B):629-33.
Csatary LK, et al., (1998) Preliminary report of a controlled trial of MTH-68/B virus vaccine treatment in acute B and C hepatitis: a phase II study. Anticancer Res.18(2B):1279-82.

Company Overview

VectorLogics, Inc. is a privately-held biotechnology company focused on the development of novel cancer therapeutics and therapeutic vaccines for viral liver diseases. The Company is using its patented gene transfer technologies to create product candidates that address major unmet medical needs. Additional information on Vectorlogics is available at its web site, located at www.vectorlogics.com.

For more information contact:
Dr. Imre Kovesdi,
Chief Executive Officer
Phone:(301) 963-1641
Fax: (240) 238-2741
ikovesdi@vectorlogics.com