NABI BIOPHARMACEUTICALS

KEY FACTS ABOUT HEPATITIS C AND CIVACIR™

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Hepatitis C virus (HCV) is the most common chronic blood-borne infection in the United States and a leading cause of liver failure and liver cancer.[1] The U.S. Centers for Disease Control and Prevention (CDC) estimates that approximately 3 million individuals in the U.S. are chronically infected with HCV,[2] and the World Health Organization (WHO) estimates 170 million individuals worldwide are infected with HCV.[3] The virus can be transmitted through blood transfusion, organ transplants, intravenous drug use, kidney dialysis and sexual contact.[4]

Approximately 75 percent of acutely infected individuals become chronic carriers of HCV — a condition that usually results in insidiously progressive liver disease.[5] The CDC reports that up to 5 percent of those infected with chronic HCV develop liver failure or liver cancer, requiring a liver transplant in order to survive.[4] Of the nearly 5,000 liver transplants performed in the U.S. in 2002, the majority were due to complications from HCV.[6] In chronic HCV patients who receive liver transplants, the rate of HCV recurrence is nearly 100 percent.[7] When HCV infection occurs in transplant patients, it contributes to failure of the transplanted liver and frequent hospitalizations.[7]

HCV is linked to some 10,000 to 12,000 deaths in the U.S. each year.[5] Costs due to HCV infections are estimated to exceed $600 million a year.[8]

WHAT IS CIVACIR?

Civacir™ (Hepatitis C Immune Globulin, Human) is an investigational human polyclonal antibody product being developed by Nabi Biopharmaceuticals. It contains antibodies to HCV. Civacir is being developed to prevent hepatitis C disease in HCV-positive liver transplant patients. Civacir is also being evaluated for the treatment of chronic hepatitis C virus infections.

Civacir is derived from human plasma enriched with HCV antibodies. Nabi Biopharmaceuticals collects plasma with HCV antibodies from screened donors at the company's nine U.S. Food and Drug Administration (FDA)-licensed plasmapheresis collection centers. A process known as "fractionation" purifies and concentrates the antibodies that neutralize HCV. The antibodies in Civacir have been shown in animal studies to neutralize HCV.

CURRENT THERAPIES

The three currently licensed therapies for hepatitis C virus — peginterferon, interferon and ribavirin — have limited efficacy in chronically infected patients. When used alone or in combination, efficacy ranges from 20 to 50 percent. The remaining 50 percent of patients respond moderately or not at all to these medications.[9] In addition, currently available therapies cannot be used to protect liver transplant patients from HCV re-infection after surgery. As a result, among chronic HCV patients who undergo liver transplantation, HCV recurrence in the transplanted liver is nearly universal.[7]

MARKET OPPORTUNITY

Civacir would be the first therapy to prevent hepatitis C re-infection in liver transplant patients. Nabi Biopharmaceuticals estimates the worldwide market opportunity for Civacir is $150 million to $200 million a year.

CLINICAL DEVELOPMENT

Nabi Biopharmaceuticals is developing Civacir using the post-transplant administration of Hepatitis B Virus Immune Globulin (HBVIg) as a model. Studies have shown that treatment of HBV-infected liver transplant patients with high doses of HBVIg for extended periods of time following transplantation have been successful in preventing re-infection with HBV in up to 93 percent of patients.[10] In preclinical models, multiple infusions of Civacir similarly controlled HCV replication.

The National Institutes of Health (NIH) has funded and conducted a Phase I/II clinical trial of Civacir in HCV-positive liver transplant patients at four study sites in the U.S. This randomized, controlled study evaluated the safety of dosing patients with Civacir during and after transplant surgery, the level of HCV-specific antibodies in trial subjects following dosing, liver enzyme levels (a measure of liver damage) and HCV levels in the transplanted livers. Data from the trial were reported in February 2004 and revealed that Civacir was well tolerated in liver transplant patients and produced a trend towards a reduction in ALT (serum alanine aminotransferase, an important liver enzyme that measures liver function) levels. Based on the results from this trial, Nabi Biopharmaceuticals expects to be able to define the continued development strategy for Civacir following discussions with the FDA.

In December 2002, Civacir was granted Orphan Drug Designation by the FDA for the prevention of hepatitis C infection in liver transplant recipients.

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