Idenix PHARMACEUTICALS

HCV

HEPATITIS C FACT SHEET

ABOUT HEPATITIS C

Hepatitis C is an infectious liver disease caused by the hepatitis C virus (HCV).[1] It is the most common chronic blood-borne infection in the United States.[2] HCV infection becomes chronic in about 80%[1] of individuals after their initial infection. Chronic HCV infection is characterized by inflammation of the liver, causing progressive liver damage that can lead to cirrhosis (liver scarring), hepatocellular carcinoma (liver cancer), liver failure, and death.[1] Hepatitis C-related liver failure is the leading indication for liver transplantation in the United States.[3] Globally, HCV is responsible for 50–76% of all liver cancer cases, and two thirds of all liver transplants in the developed world.[4]

Chronic HCV generally progresses slowly; evidence of liver disease typically appears 10 to 40 years after initial infection.[1,5] In its early stages, chronic HCV is often asymptomatic or causes non-specific symptoms such as fatigue or loss of appetite.[1] For this reason, many people with chronic HCV are unaware of their condition.

TRANSMISSION OF THE HEPATITIS C VIRUS

Currently, there is no vaccine that can prevent HCV infection.[1] HCV is most commonly spread by contact with contaminated blood.[1] In Western countries, current and former injecting drug users, recipients of unscreened blood products (prior to early 1990s), dialysis patients, and hemophiliacs constitute the highest risk groups for the acquisition of HCV.[1] Additional risks for infection include receiving an organ transplant prior to 1992, and lower risks such as, unprotected sex with multiple partners, birth from an infected mother, and needle-stick injuries sustained by health care workers.[3] In developing countries, primary sources of HCV transmission may also include the use of unsterilized equipment for either medical procedures or other procedures, such as ear/body piercing, circumcision, or tattooing.[1] In the United States, many patients acquired chronic HCV infections prior to 1989 by exposure to contaminated blood products during surgery or other medical procedures.[1]

The advent of diagnostic tests for HCV in the early 1990s led to marked improvements in preventing HCV infections, through screening of the blood supply and patient education.[6] Currently, diagnostic tests are able to detect HCV antigens, antibodies, and HCV RNA in the blood of infected patients.[1] These tests are essential tools for identifying patients and managing therapy, and have led to a sharp decline in the frequency of new HCV infections in the United States.[1] However, due to the slow progression of HCV after initial infection and to the relatively low rate of spontaneous viral clearance among chronically infected individuals, the prevalence of chronic HCV infection and progressive liver disease remains high.[7]

EPIDEMIOLOGY AND ECONOMIC BURDEN OF HEPATITIS C

The U.S. Centers for Disease Control and Prevention estimates that about 4.1 million persons in the U.S. have been infected with HCV, and 3.2 million of these people are chronic HCV carriers.[8] The World Health Organization estimates that 170 million individuals worldwide have been infected with HCV, with 3 to 4 million new people being infected each year.[1] The overall prevalence of HCV infection in the population varies from 0.5% to 2% in Europe and North America, to about 5% in Africa and the Eastern Mediterranean region.[1]

Although the rate of new HCV infections has declined, the burden of hepatitis C on patients and healthcare systems is expected to continue to rise over the next two decades.[7] In large part, this is due to continued disease progression among the many individuals infected prior to 1990. The population of chronically infected HCV patients who are at risk of progressive liver disease is projected to increase significantly prior to 2020.[7] The associated rise in serious disease outcomes such as decompensated liver cirrhosis, liver cancer and liver transplantation is expected to greatly increase the burden on healthcare resources required for the treatment of patients with chronic hepatitis C.[7]

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Costs for providing care for patients with HCV-associated liver disease in the United States are estimated to be more than $750 million[9] annually, and this cost is likely to increase in proportion to the expanding diagnosed patient population.[7] As the prevalence of severe liver disease attributable to chronic hepatitis C rises, deaths due to complications from it, which are currently 8,000 to 12,000 per year in the United States, are expected to increase 180% over the next 20 years.[7]

TREATMENT OF CHRONIC HEPATITIS C AND NEED FOR NEW THERAPIES

Although treatment for chronic hepatitis C has improved markedly since the early 1990s, there continues to be a large unmet medical need in the area of hepatitis C therapy. The last major advance in hepatitis C therapy was the advent of combination regimens of pegylated interferon and ribavirin in 2001. This innovation increased the rate of sustained viral response (SVR)* to between 40% and 50% in treatment-naïve patients infected with the genotype 1 strain of HCV, the most common and most difficult-to-treat strain of HCV.[6] HCV genotype 1 accounts for 60% of all global HCV infection[10] and for more than 70% of reported cases of hepatitis C in the U.S. and Japan.[11] Genotype 1 is by far the predominant HCV genotype in western Europe.[12]

This need to improve response rates has led to the discovery and development of many investigational products for treatment-naïve patients, as well as for the many patients where pegylated interferon and ribavirin therapy has failed.

*SVR is defined as the absence of demonstrable virus replication six months post treatment.

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