

New treatment for chronic hepatitis C genotype 1 addresses major public health need

 VICTRELIS[®] targets the virus directly, helping patients who have failed previous therapy or are new to treatment significantly improve their chances of clearing the virus compared to current standard treatment -

DUBLIN [20th June 2012 @ 0800 hrs] – VICTRELIS® (boceprevir), one of a new class of treatments for chronic hepatitis C (CHC) genotype 1 infection, is launched today by healthcare company MSD. It will be used in combination with current treatments (peginterferon alfa and ribavirin) in adult patients with early stage liver disease who are previously untreated or who have failed previous therapy. (1a)

Hepatitis C is a major cause of liver disease worldwide^(2a), the WHO estimates that approximately 3% of the world's population (180 million) is infected ⁽³⁾. A significant challenge is that many of those who are infected do not show symptoms for a long period and consequently diagnosis is often delayed. As a result, hepatitis C is often described as the 'silent' epidemic ⁽⁴⁾. 75% of those infected fail to clear the virus and develop chronic infection. ^(2b) Between 5 – 20% of those chronically infected individuals develop cirrhosis of the liver after 20 years of infection. ^(2b) Of those with cirrhosis, 1.5 - 2.5% will go on to develop liver cancer each year. ^(2b)

Dr Stephen Stewart, Consultant in Gastroenterology and Hepatology, Mater Hospital, Dublin commented, "The launch of VICTRELIS for chronic hepatitis C genotype 1 is very exciting and meets a major public health need. Finally we have new options for patients with the hardest to treat form of the disease. Patients who have failed previous therapy or are new to treatment can significantly improve their chances of clearing the virus compared to current standard treatment."

In Ireland, 1,239 new cases of hepatitis C were reported in 2010 (67% males and 32% females. The sex was not known in 10% of cases). (2c) The highest notification rates were in young to middle aged adults. (2d) The prevalence in the general population is low and most cases fall into defined risk groups such as injecting drug users, people who received unscreened blood or blood products in the past and people who were born in hepatitis C endemic countries. (2e) The overall prevalence of chronic hepatitis C in Ireland is comparable to other Northern European countries. (2f)

"MSD's long standing commitment in hepatitis C virus spans three decades. It represents an important step forward for people living with hepatitis C and the healthcare professionals who treat them. VICTRELIS has been deemed to be highly cost effective by the National Centre for Pharmacoeconomics (NCPE) and will help lower the number of people with hepatitis C developing chronic liver disease, cirrhosis and requiring liver transplants. "Commented Dr. Colm Galligan, Medical Director, MSD, which employs 2,300 across five counties in Ireland.

VICTRELIS, is a Direct Acting Antiviral (DAA) agent designed to interfere with the ability of the hepatitis C virus to replicate by inhibiting a key viral enzyme. Current standard therapy for chronic hepatitis C works to strengthen the body's natural immune response to the virus, but a majority of patients with chronic hepatitis C genotype 1 are not able to achieve a sustained virological response (SVR) meaning that six months after treatment, the patients still have a detectable hepatitis C virus in the blood. (1b)

The hepatitis C virus is primarily transmitted through sharing contaminated equipment when injecting drugs or through receipt of unscreened blood or blood products. Sexual, occupational and perinatal (the period immediately before and after birth) transmission can also occur but are less common. (2g)

-ENDS-

Notes to Editor

More Information on VICTRELIS (Boceprevir)

Please refer to the Summary of Product Characteristics (SPC) available on www.medicines.ie

MSD

Today's MSD is a global healthcare leader working to help the world be well. MSD is known as Merck in the United States and Canada and MSD elsewhere. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our

commitment to increasing access to healthcare through far-reaching policies, programmes and partnerships.

MSD in Ireland

MSD employs 2,300 people directly in Ireland through its operations at sites in Carlow, Cork, Dublin, Tipperary and Wicklow.

In the last five decades the company has invested over €2.2bn in Ireland. MSD is one of Ireland's leading exporters and contributes significantly towards making the pharmaceutical industry the country's leading export sector. MSD is a member of Guaranteed Irish and manufactures or packages many of its leading products for the world market in Ireland. For more information, visit www.msd.ie.

MSD's global commitment to advancing hepatitis therapy

MSD is committed to building on its strong legacy in the field of viral hepatitis by continuing to discover, develop and deliver vaccines and medicines to help prevent and treat viral hepatitis. In hepatitis C, company researchers developed the first approved therapy for chronic HCV in 1991 and the first combination therapy in 1998. In addition to ongoing studies with boceprevir, extensive research efforts are underway to develop additional innovative oral therapies for viral hepatitis treatment.

Peginterferon alfa which will be prescribed in conjunction with ribavirin and VICTRELIS, is manufactured by MSD in Brinny, Co. Cork

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References

- Summary of Product Characteristics for VICTRELIS
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- Ghany MG, Strader DB, Thomas DL, Seeff LB. Diagnosis, management and treatment of hepatitis C: An update. Hepatology. 2009;49(4):1335-1374
- HPS. Hepatitis C <u>HTTP://WWW.HPS.SCOT.NHS.UK/BBVSTI/HEPATITISC.ASPX</u> (accessed 26.05.11)
- Hutchinson JG, Lawwitz, EJ, et al. Peginterferon Alfa-2b or Alfa-2a with Ribavirin for treatment of hepatitis C infection: NEFM Vol 361;6,580-593.