

BMS strengthens hepatitis portfolio

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BMS aims to improve on existing Interferon-based standard of care in conjunction with Peg Interferon and Ribavirin, and Interferon and/ or Ribavirin to minimize resistance of hepatitis C virus

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According to statistics, more than two billion people show evidence of hepatitis B virus (HBV) infection. About 350 million people have chronic HBV. Globally, 170 million people have chronic HCV infection and 20-30 percent of chronically infected will develop cirrhosis, one-third of which will progress to hepatocellular carcinoma (HCC). Hepatitis C virus (HCV) is the leading indication for liver

Identifying the need to curb hepatitis, Bristol-Myers Squibb (BMS), the global biopharma company, has intensified its activities to find remedy for HBV and

“Asia Pacific region is becoming the hotbed for HBV and HCV and that in-turn reflects an increase in the liver cancer cases. There is an urgent need to manage and restrict liver cancer by following an integrated approach,” says Mr Andreas stol-Myers Squibb.

Hepatitis B

Untreated hepatitis B is responsible for one million deaths worldwide each year. Giving insights on the initiatives taken by BMS to restrict HBV, Mr Paul Slade, executive director – virology, Bristol-Myers Squibb, says, “Hundreds of millions of people

in the Asia Pacific region are at risk of developing severe liver disease, it is high time to find a promising remedy for this. The main challenge in tackling chronic hepatitis B is to find a complete cure. BMS' Baraclude is a leading treatment regimen for chronic hepatitis B patients. Over 430,000 patients were treated in the past five years worldwide."

Baraclude (entecavir) was discovered by BMS as part of a large screening program to identify antiviral treatments. Baraclude was originally being investigated as a potential compound to treat the herpes viruses. It soon emerged that Baraclude had properties that made it a valuable drug candidate to treat the hepatitis B virus, demonstrating potent antiviral activity and high selectivity. Bristol-Myers Squibb embarked on more than eight years of clinical research, which ultimately demonstrated that Baraclude has been identified as a potent, oral antiviral therapy that can effectively reduce viral load to undetectable levels (<300 copies/mL) in the majority of patients chronically infected with hepatitis B.

Baraclude has been approved for adults with chronic hepatitis B in several Asia Pacific countries including China and India (2005); Japan, Korea and Taiwan (2006); and Hong Kong (2007).

Hepatitis C

"The combination of PEG Interferon and Ribavirin is the current treatment option for HCV. About 50-80 percent of patients can be cured depending on the viral genotype, but there are associated adverse events including depression, fatigue, flu-like symptoms, and anemia. Duration of therapy for most HCV genotypes is 48-week with PEG Interferon and Ribavirin. The HCV strategy at BMS is three-pronged with the aim of improving treatment options across all genotypes, enhancing Interferon therapy (IFN-alpha) +/- small molecule antivirals, developing combinations of oral antivirals, +/- IFN and/or Ribavirin. Another compound, Brivanib is under broad-spectrum phase III development plan for Brivanibin unresectable HCC," adds Mr Slade.

"In India, more than 30 million people are infected with HBV and 19 million with HCV. In 2011, the government of India has made HBV a priority disease area. All children born in India will now receive HBV vaccine"

— **Ms Phangisile Mtshali Manciya**, director – Delivering Hope, Bristol-Myers Squibb Foundation

The phase II study of BMS investigational compound for HCV — Pegylated Interferon Lambda (PegIFN Lambda) — showed safety, viral response, and impact of host genotype. Based on current data, PegIFN Lambda shows promise across a broad range of doses and viral genotypes. Study is ongoing; and the results are expected by the end of 2011. BMS' HCV DAAs NS5A Replication Complex Inhibitor (BMS-790052) and NS3 Protease Inhibitor (BMS-650032) are in phase II. BMS aims to improve on existing Interferon-based standard of care in conjunction with Peg Interferon and Ribavirin, and Interferon and or Ribavirin to minimize resistance of HCV. Broad-spectrum phase III development plan of BMS is ongoing for another inhibitor — Brivanib — in HCC. Brivanib Biomarker Program is exploring potential biomarkers that may predict efficacy and safety.

Delivering hope

Delivering Hope is an initiative of BMS Foundation, an independent philanthropic wing of BMS, to prevent hepatitis in Asia. The foundation is taking several initiatives in China and India. Ms Phangisile Mtshali Manciya, director – Delivering Hope, Bristol-Myers Squibb Foundation, said, "The foundation targets funding and takes initiatives to improve health outcomes at the community level; takes care of community mobilization and supportive services; and provides trainings to healthcare workers. The Foundation has awarded four new grants in China and India totaling nearly \$1 million."

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— **Mr Andreas Pangerl**, global medical lead – hepatitis, Bristol-Myers Squibb

Commenting on the initiatives taken in China and India, Ms Manciya, says, "In China, approximately 40 million people are infected with HCV. Testing for hepatitis is not accessible to more than 50 percent of the population. The Chinese government has declared HCV an urgent public health issue and named it as one of China's top five deadly epidemics. Delivering Hope has made great strides in China since 2002, by policy outreach and contributing to the development of HCV operational research across the country."

"In India, more than 30 million people are infected with HBV and 19 million with HCV. In 2011, the government of India has made HBV a priority disease area. All children born in India will now receive HBV vaccine. The initiatives taken by Delivering Hope in India include the Hepatitis Foundation of Tripura (HFT) Vaccination Program; the Health Oriented Programs Education (HOPE) initiative for generating awareness of HBV in school children; development of a curriculum that can be adapted by local teachers across the school system in Uttar Pradesh; and to address the high hepatitis infection rates in the area, the United Way of Mumbai, together with Delivering Hope have developed a comprehensive targeted hepatitis

education program," she concludes.

With Asia Pacific region gaining prominence because of the high prevalence of hepatic disease, BMS' positive trial outcomes and other preventional initiatives raise confidence.

Pradeep Kumar in Bangkok

The author was in Bangkok at the invitation of Bristol-Myers Squibb