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PRESS RELEASE

FOR IMMEDIATE RELEASE

**Liver Disease Congress Introduces New Treatment Guidelines
for Sufferers of Chronic Hepatitis B**

New findings may enhance the lives of millions of infected Asians

(Hong Kong, 12 June, 2008) – Liver disease specialists from across Greater China came together today at the opening press briefing of the Hong Kong-Shanghai International Liver Congress to announce new developments of a treatment guideline for chronic hepatitis B (CHB).

The updated guideline for hepatitis B management has been created under the auspices of the Asian-Pacific Association for the Study of the Liver (APASL). Like its predecessor, it helps to define and shape the many health policies and good clinical practices regarding hepatitis B in the region, greatly enhancing the level of detection and care for people suffering from this potentially fatal virus.

Prof. George K.K. Lau, President of APASL and the Secretary General of the Hong Kong – Shanghai International Liver Congress said, “CHB is most prevalent in the Asia-Pacific region where 75 percent of the world’s 350 million chronic carriers reside and China is one of the most heavily impacted countries with about 93 million people afflicted with CHB.”

He said “Our clinical experience and research continuously provides us with new insights in addressing many unresolved issues and new methods of managing CHB.” For example, he said, due to the large amount of new data available in the past three years, one big development in the fight against hepatitis B has been a decision by the APASL Planning Committee on CHB to make a major update to the APASL guideline, which defines many of the procedures and practices in treating those infected.

Goal of Therapy

There is no cure for CHB. The primary goal of treatment is to permanently suppress the hepatitis B virus and keep it at a very low level.

When to start

A doctor will review the patient’s ALT, which is the level of enzymes and the level of “HBV DNA” which reflect the amount of hepatitis B virus in the patient’s body to determine when to start treatment.¹ At the same time the physician will also check the HBeAg sero-marker.

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What kinds of treatment

When the previous version of the guideline was published in 2005, the treatment of CHB had already advanced into the era of oral medication. However, those early remedies had relatively limited long-term efficacy.ⁱⁱ

Over the past three years, medical advances have greatly bolstered the ammunition available in the fight against CHB. The latest guideline added two new oral CHB treatments, telbivudine and entecavir, as 1st line medication.

Patients who have contracted CHB now have a broader choice of treatment after the introduction of these two new treatments (telbivudine and entecavir). This is particularly important for special groups of CHB patients such as pregnant women, as this is the first time APASL guideline recommends women who become pregnant while on oral antiviral drugs can continue treatment with category B treatment.*

Monitoring schedule and indicators

The guideline also recommends patients who are on treatment should be monitored at least once every three months, paying particular attention to two important indicators:

- HBV DNA level – indicating the amount of virus in the blood
- e-seroconversion – indicating a loss of detectable e antigen (a viral protein that is secreted by HBV-infected cells) in the blood and production of antibodies, signaling an increased immune response to the hepatitis B virus infection. This is important to patients because after e-seroconversion they may be able to stop therapy and are less likely to develop liver disease.

When to stop treatment?

The guideline recommends HBeAg positive patients who achieve e-seroconversion and non-detectable HBV DNA on two separate occasions at least six months apart, can consider stopping treatment.ⁱ

HBeAg negative patients, who achieve non-detectable HBV DNA on three separate occasions at least six months apart, can consider stopping treatment. This group of patients tends to be older, been infected longer and are more difficult to treat.

Implications to Patients

Another speaker at the media briefing, Prof. Jin-Lin Hou, Director and Professor, Department of Infectious Diseases, Nanfang Hospital, Guangzhou, China. In his presentation, he stressed the importance of regular HBV DNA monitoring, especially at week 24.

Prof. Hou remarked, “The on-treatment 24-week HBV DNA monitoring is a useful indicator for clinicians to predict success of a treatment, enabling them to implement an alternative strategy if necessary. It allows us time to adjust treatment before the disease progresses. In addition, the possibility of having a recess of treatments alleviates patients’ fear of the financial burden brought on by continuous, life-long therapy.”

He further substantiated the importance of week 24 by highlighting recent research which shows that an HBeAg positive patient** who has been treated with telbivudine and has achieved undetectable HBV-DNA level at week 24 will have a around 50 percent chance of achieving e-seroconversion at the end of two years.ⁱⁱⁱ Almost 90 percent of those will remain HBV-DNA undetectable studies indicate.”

Prof. Lau added, "With a broad portfolio of hepatitis B treatments and a structured viral monitoring strategy, we can now be more optimistic about outcomes for patients suffering from CHB than ever before."

The Hong Kong-Shanghai International Liver Congress meets biannually. This year it runs from today to 15 June 2008 at the Hong Kong Convention and Exhibition Centre. More than 2,000 distinguished liver specialists around the world will present their latest findings and unique experiences in the study and treatment of different types of liver disease, including CHB.

The APASL guideline was developed via a consensus reached by a Core Planning Committee of leading clinicians from 10 countries in the region. The Committee formed five working parties, comprising 37 members, who reviewed current literature as well as relevant unpublished data, and debated the significance of their reported findings to ultimately produce a set of Consensus Recommendations for the future treatment of hepatitis B. All the Recommendations are based on firm clinical evidence drawn from scientific studies conducted to the highest standards. The Consensus Recommendations encompass hepatitis B prevention, the natural history of the disease, current treatment options, optimal lengths of treatment, and recommendations for future clinical studies.

CHB infection is an important health problem worldwide. The hepatitis B virus is 50 to 100 times more infectious than HIV and patients who have chronic infections have no symptoms. About 25 per cent of carriers eventually die from liver cancer or cirrhosis.^{iv}

Notes to Editor :

* Pregnancy Category Bⁱⁱ is a safety rating used by US Food and Drug Authority. Drugs in this category shown that animal reproduction studies do not demonstrate a risk to the fetus however there are no adequate and well-controlled studies in pregnant women

** CHB HBeAg positive patients with ALT>2X ULN and HBV DNA > 100,000 copies/ml (2.0x 10⁴ IU/ml)

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ⁱⁱⁱ An abstract presented at American Association for the Study of Liver Diseases (AASLD) Annual Meeting; November 2-6, 2007; Boston, MA, USA.

^{iv} Centers for Disease Control and Prevention. Hepatitis B fact sheet. Available at www.cdc.gov/ncidod/diseases/hepatitis/b/fact.htm. Accessed 3/6/07.