



CME AND FACULTY INFORMATION

CME INFORMATION

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the University of Wisconsin Medical School and MDG/HBV *Watch*[®].

The University of Wisconsin Medical School designates this continuing medical education activity for a maximum of 0.75 category I credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours that he/she actually spent in the educational activity.

To receive the 0.75 category I credit of CME credit, you must complete the following quiz satisfactorily (70% correct answers) and record your answers at the bottom of the CME Web Activity Evaluation Form which follows the quiz.

We are grateful for the independent educational grant provided by Bristol-Myers Squibb Company in support of this educational activity.

FACULTY INFORMATION AND DISCLOSURE

Robert G. Gish, MD, is a hepatologist and medical director of the Liver Disease Management and Transplant Program at the California Pacific Medical Center in San Francisco, California as well as Division Chief of the Section of Hepatology and Complex Gastroenterology within the Physicians Foundation at California Pacific Medical Center. Dr. Gish is also an Associate Clinical Professor of Medicine at the University of Nevada in Reno and an Associate Clinical Professor of Medicine at the University of California, San Francisco.

Dr. Gish received his undergraduate training in pharmaceutical sciences at the University of Kansas in Lawrence and his medical degree from the University of Kansas in Kansas City. After graduation, he went on to complete his internship and residency in internal medicine at the University of California, San Diego, and a fellowship in gastroenterology and hepatology at the University of California, Los Angeles.

Dr. Gish is board certified in internal medicine and gastroenterology. He is also a member of the American Association for the Study of Liver Diseases, the American Gastroenterological Association, the American Society of Transplant Physicians, and the International Liver Transplant Society, among others. In addition, Dr. Gish has published more than 100 original articles, reviews, abstracts, and book chapters regarding all aspects of liver disease and transplantation and is a widely requested speaker both nationally and internationally.

Dr. Gish will discuss commercially available products during his lecture. His presentation will also reference unlabeled/unapproved uses of drugs or products.

Dr. Gish has received grant/research support from Amgen Inc., Ortho Biotech, Roche Laboratories Inc., Schering-Plough Corporation and SciClone Pharmaceuticals. Dr. Gish has acted as a consultant to Achillion Pharmaceuticals, Akros Pharma, Amgen, Anadys Pharmaceuticals, Inc., Bayer, Bristol-Myers Squibb Company, Centocor, Inc., Chiron Corporation, Exagene, Eximious, Gilead Sciences, GlaxoSmithKline, Human Genome Sciences, Inc., ICN Ribapharm, InterMune, Inc., Metabasis Therapeutics, Inc., Oral Vaccine Technology/BRM, Ortho Biotech, Roche Laboratories Inc., Schering-Plough Corporation, United Therapeutics Corporation, and XTL Biopharmaceuticals LTD.

“Clinical Trial Results of New Therapies for Hepatitis B”

A CME-accredited Guest Web Lecture

CD--CME Activity – Quiz

To receive the 0.75 category I credit of CME credit, you must complete the following quiz satisfactorily (70% correct answers) and record your answers at the bottom of the CME Web Activity Evaluation Form which follows the quiz:

***Please circle the correct response**

1. Current treatment of hepatitis B remains suboptimal due to:
 - a. Modest response rates
 - b. Development of resistance
 - c. Side effect concerns for some products
 - d. All of the above

2. New drug applications to the US Food and Drug Administration have recently been made for entecavir and peginterferon alfa-2a for the treatment of hepatitis B.
 - a. True
 - b. False

3. In the ETV-022 study by Chang and colleagues of entecavir versus lamivudine in nucleoside-naïve HBeAg-positive patients, greater histologic improvement at week 48 was seen in:
 - a. Entecavir-treated patients
 - b. Lamivudine-treated patients

4. In the ETV-022 study by Chang and colleagues of entecavir versus lamivudine in nucleoside-naïve HBeAg-positive patients, what was the virological response, defined as HBV DNA level <400 copies/mL at week 48 with entecavir?
 - a. 38%
 - b. 53%
 - c. 69%
 - d. 71%

5. In the ETV-027 study by Shouval and colleagues of entecavir versus lamivudine in nucleoside-naïve HBeAg-negative patients, the primary efficacy endpoint was:
 - a. Ishak fibrosis score and ALT <1.25 x ULN
 - b. ≥ 2 -point decrease in Knodell necroinflammatory score and no worsening of fibrosis

6. In the ETV-026 study by Sherman and colleagues of entecavir versus lamivudine in lamivudine-refractory HBeAg-positive patients, the mean change in HBV DNA (PCR) was -0.48 for lamivudine and -5.14 for entecavir
 - a. True
 - b. False

7. In an ongoing analysis of HBV resistance, the level of genotypic resistance observed after one year of therapy with entecavir is:
 - a. 0% in HBeAg-positive and HBeAg-negative nucleoside-naïve patients
 - b. 2% in HBeAg-positive and HBeAg-negative nucleoside-naïve patients
 - c. 6% in patients with pre-existing lamivudine mutations (lamivudine-refractory disease)
 - d. a and c

8. In the study by Janssen and colleagues comparing peginterferon alfa-2b monotherapy versus combination with lamivudine, which of the following conclusions was NOT supported by the data:
 - a. One year of peginterferon alfa-2b is effective for HBeAg-positive chronic hepatitis B
 - b. In comparison to peginterferon alfa-2b monotherapy, the combination of peginterferon alfa-2b plus lamivudine leads to a higher sustained response
 - c. In comparison to peginterferon alfa-2b monotherapy, the combination of peginterferon alfa-2b plus lamivudine leads to a higher end-of-treatment response but the sustained response was equal
 - d. Peginterferon alfa-2b treatment should be stratified by genotype

9. In the study by Marcellin and colleagues assessing peginterferon alfa-2a with and without lamivudine versus lamivudine alone in HBeAg-negative chronic hepatitis B, which of the following conclusions was NOT supported by the data:
 - a. Peginterferon alfa-2a monotherapy shows significantly higher response rates at 24 weeks post-treatment for both ALT and HBV DNA, as compared with lamivudine monotherapy
 - b. The combination of peginterferon alfa-2a + lamivudine did not improve response rates compared with peginterferon alfa-2a alone
 - c. The combination of peginterferon alfa-2a + lamivudine showed significantly improved response rates compared with peginterferon alfa-2a alone
 - d. No unexpected adverse events were reported with peginterferon alfa-2a, and the addition of lamivudine did not alter the safety profile

10. In the study by Lau and colleagues assessing peginterferon alfa-2a with and without lamivudine versus lamivudine alone in HBeAg-positive chronic hepatitis B, which of the following conclusions was NOT supported by the data:
 - a. Peginterferon alfa-2a showed significantly higher 24-week post-therapy response rates compared to lamivudine for HBeAg seroconversion, HBV DNA response and ALT normalization
 - b. The combination of peginterferon alfa-2a and lamivudine did not improve post-therapy response rates compared with peginterferon alfa-2a alone
 - c. Withdrawals from study medication were low across all three treatment groups
 - d. HBsAg seroconversion was not reported for any patient



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CME WEB ACTIVITY EVALUATION

Clinical Trial Results of New Therapies for Hepatitis B

1. Please evaluate this educational activity as a whole by filling in the appropriate circle:

	Excellent	Very Good	Good	Fair	Poor
USEFULNESS	⑤	④	③	②	①
QUALITY	⑤	④	③	②	①
AUDIO-VISUALS	⑤	④	③	②	①

2. Learning Objectives

Were the following learning objectives met?

- Be aware of emerging new therapies for HBV infection under clinical development Yes No
- Be familiar with the clinical trial results of entecavir, a new antiviral agent for the treatment of HBV infection, compared with lamivudine in HBeAg-positive, HBeAg-negative and lamivudine-refractory patients Yes No
- Evaluate the clinical trial results of peginterferon alfa-2a alone and in combination with lamivudine for the treatment of HBeAg-positive and HBeAg-negative patients Yes No

If no, please state reasons:

3. General Comments

- A. Do you feel that the program was fair, balanced, and free of commercial bias? Yes No

If no, please state reasons:

- B. Suggested topics and/or authors/presenters you would like for future educational activities:

- C. General comments about this educational activity:



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CME WEB ACTIVITY EVALUATION

Clinical Trial Results of New Therapies for Hepatitis B

D. This educational activity has contributed to my professional effectiveness and improved my ability to:

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Treat/manage patients	⑤	④	③	②	①
Communicate with patients	⑤	④	③	②	①
Manage my clinical practice	⑤	④	③	②	①

4. Faculty Evaluations

Rate the activity for each faculty member listed below.

Robert G. Gish, MD

	Excellent	Very Good	Good	Fair	Poor
Content of presentation	⑤	④	③	②	①
Ability to convey the subject matter clearly	⑤	④	③	②	①

Do you feel that this presentation was fair, balanced, and free of commercial bias? Yes No

ANSWER SHEET

Instructions

In order to complete this program successfully, you must:

- Complete the post-test.
- Complete the program evaluation form.
- Mail or fax your completed answer sheet and program evaluation to:

University of Wisconsin Medical School CME
2701 International Lane #208
Madison, WI 53704
FAX: (608) 240-2151

In order to ensure scoring, the answer sheet must be received by December 2005.

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| 1. <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D | 6. <input type="radio"/> True <input type="radio"/> False |
| 2. <input type="radio"/> True <input type="radio"/> False | 7. <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D |
| 3. <input type="radio"/> A <input type="radio"/> B | 8. <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D |
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| 5. <input type="radio"/> A <input type="radio"/> B | 10. <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C <input type="radio"/> D |

