Roche

Investor update

August 22, 2002

Roche Molecular Systems initiates U.S. clinical trials of COBAS AmpliScreenTM HBV Test
Researchers: Study of shed new light on highly infectious, often "silent", transfusion-transmitted virus, Hepatitis B

Roche Molecular Systems, Inc. (Roche) today announced the start of comprehensive clinical trials of its COBAS AmpliScreen™ HBV Test. The trials mark an important milestone because, for the first time in the U.S., Roche's PCR nucleic acid amplification technology (NAT) test will be evaluated for its safety and effectiveness in screening blood donations for the Hepatitis B virus (HBV). In the process, researchers expect to gain a clearer understanding of the prevalence of HBV.

"The clinical trials of the AmpliScreen test will help us learn more about HBV by identifying cases earlier in the course of infection," said Paul V. Holland, MD, chief executive officer and medical director of BloodSource, and a principal investigator in the study. "We may also identify chronic, low-level HBV carriers who have not made a serologic response yet, but who nonetheless present a transmission risk, which would help us further optimize blood safety."

Serological tests currently approved to screen blood donations usually just detect a person's antibodies to a viral infection, but these antibodies take time to develop - a period known as a "serologically silent window" or preseroconversion window period. In 1996, the National Heart, Lung, and Blood Institute's Retrovirus Epidemiology Donor Study (REDS) estimated that one in 63,000 donations in the United States were made during the preseroconversion window period, thus posing a risk for transmission of HBV infection.

The AmpliScreen Test is able to amplify a single molecule of viral DNA or RNA billions of times, and is therefore capable of directly revealing the presence of viral genetic material in blood, which may contribute to narrowing the window period.

"It is important that we conduct a trial to determine the efficacy of this approach for hepatitis B, particularly in the context of pool testing, and finding additional sensitivity to achieve a reduction in HBV window cases over and above current licensed and unlicensed assays," noted D. Michael Strong, PhD, executive vice president of operations for Puget Sound Blood Center, and also involved in the trial. "The Roche test has demonstrated the most sensitive potential in this regard."

The Japanese Red Cross is already using Roche's AmpliNAT™ system to screen for HBV in their blood donations. This system was developed to meet the needs of the 5 million donations screened by the Japanese Red Cross each year since February 2000. AmpliNAT is a triplex assay capable of simultaneously screening HBV, HCV and HIV viral material.

"The experience in Japan showed the presence of more than 260 'window' cases of HBV using the more advanced NAT screening technology. It is reasonable to expect that we will identify similar results through this clinical trial," added Dr. Holland.

Roche is able to move forward with the clinical trials of its COBAS AmpliScreen HBV Test, based on receiving Investigational New Drug Application (IND) permission to proceed to clinicals from the U.S. Food and Drug Administration in July. The trials will be conducted at five of America's Blood Centers locations throughout the United States: BloodSource in Sacramento, California; Puget Sound Blood Center in Seattle, Washington; Community Blood Center of Kansas City, Missouri; Memorial Blood Center in Minneapolis, Minnesota; and Gulf Coast Regional Blood Center in Houston, Texas.

"The start of clinical trials for the COBAS AmpliScreen HBV test is an important milestone, as it will allow for the collection of data that ultimately will enhance blood screening efforts in the United States," said Heiner Dreismann, PhD, head of Roche Molecular Diagnostics. "The trials also underscore Roche's long-term commitment to blood screening, and the application of PCR technology to the public health arena."

About HBV

Although HBV can be prevented with a vaccine, in the United States approximately 5,000 people die from HBV each year. HBV is the most common serious liver infection in the world, and the leading cause of liver cancer. It is highly infectious (100 times more infectious than HIV), and more than 200,000 people contract HBV annually in the U.S. Approximately 90 percent of those infected will completely recover as their immune systems eradicate the disease; however, up to 10 percent remain carriers of HBV. In approximately 50 percent of adult cases, no symptoms are observed; however carriers are able to transmit the virus throughout their lives. There are more than one million chronic HBV carriers in the U.S., one-third of whom do not know how they were infected.*

About AmpliScreen

The COBAS AmpliScreen products, used for screening blood donations, are based on Roche's polymerase chain reaction (PCR) technology, which is now the leading nucleic acid amplification technology (NAT) in the world. Roche's PCR blood screening tests for HCV and HIV-1 are already approved for commercial use in Italy, France, Germany, Australia, and Switzerland. Poland has approved the COBAS AmpliScreen HCV Test, v2.0 for commercial use, and Spain has approved the COBAS

AmpliScreen HIV-1 Test, v1.5 for these purposes. The products are also used in other countries where registration is not required.

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* Statistics on HBV from: "Facts About Hepatitis B For Adults," National Coalition for Adult Immunization, August 2001, www.nfid.org; "WHO Fact Sheet/204," World Health Organization, October 2000, www.who.int; and The Centers for Disease Control and Prevention, "Viral Hepatitis B Fact Sheet," December 2001, www.cdc.gov.

The COBAS AmpliScreen products are available for research only use in the U.S.

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About Roche and the Roche Diagnostics Division
Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's products and services address prevention, diagnosis and treatment of diseases, thus enhancing well-being and quality of life. For more information, access www.roche.com.

Roche's Diagnostics Division, the world leader in in-vitro diagnostics with a uniquely broad product portfolio, supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide. Molecular Diagnostics, a business area of Roche Diagnostics, has made the polymerase chain reaction (PCR) the leading nucleic acid amplification technology (NAT) in the world. PCR technology allows minute amounts of genetic material to be amplified into billions of copies in just a few hours, thereby facilitating detection of the DNA or RNA of pathogenic organisms even before antibodies to these organisms are formed. Roche Diagnostics' website is located at www.roche-diagnostics.com.

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