

Basel, 5 December 2002

Roche receives FDA clearance for the Cobas AmpliScreen System

Significantly strengthens Roche's position in the blood screening business

The U.S. Food and Drug Administration (FDA) has granted clearance of Roche's Cobas AmpliScreen System. The Cobas AmpliScreen System is intended for use in laboratories testing human plasma specimens, for example to detect Hepatitis C (HCV) and Human Immunodeficiency Virus (HIV-1) viruses. The System automates the sample dilution and pooling procedures as well as the amplification and detection steps for analysis of specimens using the Polymerase Chain Reaction (PCR)-based nucleic acid amplification methods.

"This is a significant milestone for our company's PCR blood screening business," stated Heino von Prondzynski, Head of Roche Diagnostics and a member of Roche's Corporate Executive Committee. "It's extremely rewarding to see the technical, financial and human resources that we have invested for several years in this important market sector being recognized. This will help our customers to offer safer blood screening."

Roche also expects to receive FDA approval of the two PCR-based nucleic acid based technology (NAT) tests for HCV and HIV-1, which are to be used with the Cobas AmpliScreen System. Roche's AmpliScreen blood screening tests for HCV and HIV-1, are already approved for commercial use in Italy, France, Germany, Australia and Switzerland. Roche screens 100 percent of the blood supply in Japan (through its work with the Japanese Red Cross), the Netherlands and the United Kingdom, as well as more than 75 percent of Italy and France's blood donations. The products are also used in other countries where registration is not required. Sales for Roche's blood screening business are on target at 150 million Swiss Francs during 2002.

The Cobas AmpliScreen System, along with Roche's Cobas AmpliScreen HCV Test, and the Cobas AmpliScreen HIV-1 Test, have been used by America's Blood Centers since 1999 under Investigational New Drug Applications (INDs) to screen blood donations for the presence of the HCV and HIV-1 RNA viruses. This network of local, non-profit, community blood centers collects nearly half of the U.S. blood supply and a quarter of the Canadian blood supply.

"We've really seen the difference that NAT testing can make in reducing the window period, or number of days, between the time that a person contracts HIV or HCV and when the viruses can be detected using current FDA-approved serological tests," says Celso Bianco MD, Executive Vice President of America's Blood Centers and an expert on medical issues within the blood banking community. "Roche is to be commended for their ongoing commitment to automating NAT testing as it truly helps improve blood safety," he continued.

About the COBAS AmpliScreen System

The Cobas AmpliScreen System combines a commercially available pipetting/diluting instrument and an automated bench top analyzer (Roche's Cobas Amplicor Analyzer) to automate the sample preparation pooling amplification and detection steps of the Polymerase Chain Reaction (PCR) process. PCR allows scientists to copy a single segment of DNA billions of times, making it possible to take a specimen, such as a bacteria or virus containing genetic material weighing only one trillionth of a gram, and copy its genetic sequence over and over. Within hours, a test sample sufficient to confirm the presence or absence of a virus or bacteria is generated.

The Cobas AmpliScreen System is designed for use with the Cobas AmpliScreen HCV Test, version 2.0 and the Cobas AmpliScreen HIV-1 Test, version 1.5. Both tests are qualitative in vitro tests for the direct detection of Hepatitis C Virus RNA and Human Immunodeficiency Virus (HIV-1) RNA in human plasma. Roche filed a Biological License Application with the FDA for these two tests earlier this year.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups. The company's two core businesses in pharmaceuticals and diagnostics provide innovative products and services that address prevention, diagnosis and treatment of diseases, thus enhancing people's health and quality of life. The two core businesses achieved a turnover of 13.1 billion Swiss Francs in the 1st half of 2002 and employed about 57,000 employees worldwide. 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 used by researchers, physicians, patients, hospitals and laboratories worldwide.

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