

Media Release

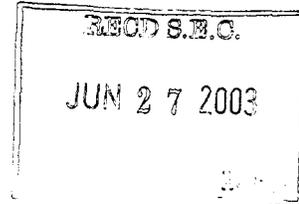


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JUL 11 2003

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Basel, 25 June 2003

Roche Diagnostics Launches the AmpliChip CYP450 in the US, the World's First Pharmacogenomic Microarray for Clinical Applications

Product powered by Affymetrix technology enables understanding of how variations in certain human genes affect metabolism of a wide variety of commercially available drugs

Roche announced today the launch of the AmpliChip CYP450 microarray in the US, the company's first microarray for clinical applications. The product enables clinical diagnostic laboratories to identify certain naturally occurring variations (called polymorphisms) in two genes, the CYP2D6 and CYP2C19, which play a major role in drug metabolism. These variations affect the rate at which an individual metabolizes many drugs used to treat cardiovascular disease, high blood pressure, depression, ADHD, and more. Knowledge of these variations, when considered with other contributing factors, can help a physician select the best drug and set the right dose for a patient sooner, as well as avoid drugs that may cause the patient to suffer serious adverse reactions. Roche expects the AmpliChip CYP450 microarray-based assay to generate annual revenues of above 100 million US-Dollars by 2008.

"The launch of the AmpliChip CYP450 microarray represents an important milestone in Roche's development of the individualized medicine market." said Heino von Prondzynski, member of the Roche Executive Committee and head of Roche Diagnostics. "Microarray technology, a logical enhancement to our patented PCR technology, is enabling Roche to develop novel diagnostic products that will help physician's move beyond a 'one size fits all' approach to medicine. We remain committed to being the first company to fully develop and commercialize this exciting technology for clinical applications."

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"The launch of this product heralds the emergence of pharmacogenetics as a medical and commercial reality," said Stephen P.A. Fodor, Ph.D., Founder, Chairman, and CEO of Affymetrix. "This product, the first of many to come from the Roche and Affymetrix partnership, is a testament to the power of our manufacturing technology to enable new solutions for improved diagnosis and patient care."

Several factors underscore the need to move beyond a one-size-fits all approach to the prescription of drugs. These include the significant percentage of people who fail to benefit from many drugs currently on the market, a significant rate of adverse events, including both serious and unpleasant side effects that can reduce a patient's compliance with the chosen treatment program. The AmpliChip CYP450 microarray represents the first diagnostic-quality tool that offers potential to address these problems, thereby contributing to an improvement in the success of the treatment and patient's quality of life, as well as to a reduction in overall healthcare costs.

In the United States alone, serious adverse drug reactions cause an estimated 100,000 deaths each year and are the fifth leading cause of death. Other adverse reactions, though not serious, are estimated to affect more than 2 million people in the US annually, creating a significant burden on healthcare systems and costs.

"There is an increasing awareness of the important role these genes play in metabolizing an estimated 20-25% drugs already on the market," said Greg Heath, Head of Roche Molecular Diagnostics Clinical Genomics Business, the area of Roche responsible for developing the test. "Targeting use of these drugs, as well as development of new drugs, to those who can most benefit from them represents an important opportunity for improving therapeutic value, reducing healthcare costs associated with a more time consuming trial-and-error approach, and improving the patient's overall experience with the chosen therapy."

Roche developed the AmpliChip CYP450 microarray on the Affymetrix microarray platform, the industry standard for research-use microarrays. In January 2003, the Roche and Affymetrix signed an agreement that gave Roche non-exclusive rights to develop human diagnostic products using core Affymetrix technologies. As part of the agreement, Affymetrix will manufacture Roche's AmpliChip microarrays.

Roche will sell the AmpliChip CYP450 microarray initially as an Analyte Specific Reagent in the United States, for use by CLIA-certified high-complexity laboratories performing CYP2D6 and CYP2C19 genotyping tests. (CLIA, or Clinical Laboratory Improvements Amendments, is a US government agency program to ensure quality laboratory testing.) Roche expects the test to be available as an in vitro diagnostic in the United States and Europe later in 2004.

Roche plans to develop additional microarray-based diagnostic tools in the areas of HIV-1 resistance genotyping, p53 cancer resequencing, colorectal cancer risk prediction, cystic fibrosis, and human papilloma virus genotyping (HPV is the leading cause of cervical cancer). These microarrays will provide information about relevant aspects of an individual's genetic make-up or reveal distinguishing characteristics of the disease or infectious agent itself that can influence choice and duration of therapy. Roche expects these new AmpliChip products to be available by the end of 2004.

About AmpliChip microarrays

AmpliChip microarrays manufactured by Affymetrix can include tens of thousands of individual DNA pieces, called probes, assembled on a thumbnail-sized glass plate, functioning like "gene antennas". Probes are used to represent genes. Hybridization is the simple, underlying principle: DNA is extracted from a sample, amplified using Roche's patented polymerase chain reaction (PCR) technology, labelled with fluorescent dye, and applied to the microarray. Genes represented in the sample will bind, or hybridize, with any complementary DNA pieces on the microarray. The resulting fluorescent dot showing where these hybridized areas occurred, is made visible through special laser technology.

About Roche and the Roche Diagnostics Division

Headquartered in Basel, Switzerland, Roche is one of the world's leading innovation-driven healthcare groups. Its core businesses are pharmaceuticals and diagnostics. Roche is number one in the global diagnostics market, the leading supplier of pharmaceuticals for cancer and a leader in virology and transplantation. As a supplier of products and services for the prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche employs roughly 62,000 people in 150 countries. The Group has alliances and research and development agreements with numerous partners, including majority ownership interests in Genentech and Chugai. 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. For further information, please visit our website www.roche.com.

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Further Information

- Picture of AmpliChip CYP450 microarray and background information: 1. Microarray ("DNA Chip") and Roche AmpliChip CYP450, 2. The CYP450 System and Drug Metabolism, 3. Personalized Healthcare

http://www.roche-diagnostics.com/press_lounge/press_releases/division/division.html

- Background on DNA chips

http://www.roche.com/pages/facets/dna_e.pdf

- Affymetrix

<http://www.affymetrix.com>