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New Abbott Gene-Based Test for Colorectal Cancer Receives CE Mark

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Des Plaines, Illinois (ots/PRNewswire) - Abbott announced today it has received CE Marking (Conformite Europeene) in the European Union for a new molecular diagnostic test, Abbott RealTime mS9 Colorectal Cancer, a non-invasive DNA assay that detects the methylated form of Septin 9, a gene linked to colorectal cancer, in blood specimens. The product is not available for sale in the United States.

The RealTime mS9 test will provide the physician with another tool in determining whether a patient should be referred for colonoscopy. It is the first automated assay for detecting the Septin 9 gene in plasma and the first cancer assay available with Abbott's m2000 PCR-based molecular diagnostic system.

Colorectal cancer is the third leading cause of cancer deaths worldwide, according to the World Health Organization. And, according to the Globocan 2002 database, there are an estimated 1 million new cases diagnosed every year. The disease originates from small, benign masses called polyps, which can become malignant after several years. Physicians, therefore, advise regular colorectal cancer screening tests after age 50 to all average risk individuals.

If detected early, the survival rate for colorectal cancer exceeds 90 percent. Unfortunately, more than half of all diagnoses occur at late stages when the prognosis is usually poor. Patient compliance with the fecal occult blood screening test on stool samples is low, the success rate is less than 50 percent and physician acceptance and use of a more convenient blood test could significantly increase the number of people being screened.

"A blood test for colorectal cancer is a significant diagnostic advance that will increase compliance with screening and help physicians diagnose more patients at early stages when the disease can be treated most successfully," said Stafford O'Kelly, head of Abbott's molecular diagnostics business. "Convenience has been a major limitation of current colorectal cancer screening methods, and the blood test addresses these long-standing concerns. If the test result is positive, the patient can be referred for a colonoscopy to confirm the finding and begin treatment."

Abbott RealTime mS9 Colorectal Cancer detects methylated DNA from the Septin 9 gene, which is shed into the bloodstream by colorectal tumors. DNA methylation is a biological process involved in cell division and scientists have published data demonstrating that it is a biomarker for colorectal cancer. In several clinical studies involving more than 3,000 samples, the new test detected 70 percent of cancers in all disease stages at 90 percent specificity. (Specificity refers to the probability that, given the absence of disease, a normal test result will exclude the disease.) By comparison, fecal occult blood tests, the only other non-invasive screening method, identify less than 50 percent of malignancies. Colonoscopy is the most accurate colon cancer screening method, but the high cost and patient reluctance to undergo this invasive procedure limits its utilization. The blood test offers a convenient, noninvasive method for identifying those patients for whom colonoscopy is indicated.

The Abbott m2000 is a clinical real-time PCR diagnostic system. Widely used in laboratories worldwide, the system performs Abbott's RealTime molecular diagnostic assays for HIV, hepatitis B and C, chlamydia, gonorrhea and human papillomavirus.

About Abbott Molecular

Abbott Molecular, abbottmolecular.com, is an emerging leader in molecular diagnostics - the analysis of DNA, RNA, and proteins at the molecular level. Abbott Molecular's instruments and reagents detect subtle but key changes in patients' genes and chromosomes. These tests have the potential for earlier detection or diagnosis, can influence the selection of appropriate therapies and may improve monitoring of disease progression.

About Abbott

Abbott is a global, broad-based health care company devoted to the discovery, development, manufacture and marketing of pharmaceuticals and medical products, including nutritionals, devices and diagnostics. The company employs more than 72,000 people and markets its products in more than 130 countries.

Abbott's news releases and other information are available on the company's Web site at www.abbott.com.

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