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New Assay Detects 100 Percent of Stage I, II and III Colon Cancers in Pre-Clinical Trials

ColoMarker™ from EDP Biotech Represents a Major Breakthrough in Early Stage Colon Cancer Detection and Treatment

Knoxville, Tenn., Sept. 16, 2009 – Marking a major milestone in the early detection and management of colon cancer, [EDP Biotech Corporation](#) (EDP), a developer of immunodiagnostic tests for humans and animals, announced today that its ColoMarker™ assay achieved 100 percent detection rate for colon cancers presented at stages I through III in pre-clinical trials. ColoMarker is the first assay of its kind to enable both early detection screening and patient management capabilities, presenting the potential to save time, money and, most importantly, lives.

“ColoMarker could radically change the way we detect and treat colon cancer,” said Kevin Jones, Ph.D., Chief Scientific Officer of EDP. “In fact, 30 percent of colon cancer deaths annually are avoidable by early screening. ColoMarker can help save lives through early detection and effective treatment. It will also help reduce healthcare costs by eliminating unnecessary colonoscopies and other procedures.”

Colon cancer is the second most prevalent cancer in the U.S., surpassed only by lung cancer. In 2009, nearly 150,000 new colon cancer cases will be confirmed and more than 55,000 people are projected to die from the disease.

ColoMarker could make accurate, early detection of colon cancer as easy as an additional blood test conducted as a routine part of patients’ annual physicals, in much the same way Prostate-Specific Antigen (PSA) tests are used to screen for prostate cancer today. The assay would become the first to combine diagnostic applications with use as a patient management tool that could help physicians determine the effectiveness of colon cancer treatment in patients.

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ColoMarker's Preliminary Potential

The pre-clinical trials, conducted from January through August 2009, evaluated 2,370 freshly drawn serum samples. ColoMarker, which uses a proprietary biomarker developed by EDP, had an overall accuracy rate of 93 percent.

When compared to the Fecal Occult Blood (FOB) test, the current clinical standard test recommended for colon cancer screening, ColoMarker performed extremely well, according to Jones. In a test panel of 243 samples drawn from patients who exhibited possible colon cancer and were referred to a specialist, the false positive rate was significantly lower for the ColoMarker assay (11 percent) than for the FOB assay (30 percent). Notably, the ColoMarker assay detected 100 percent of early-stage (Stage I) colon cancer; the FOB assay missed about 60 percent.*

"The FOB test is not 'patient friendly,' meaning that most people either refuse to use the test or cannot collect the sample effectively," continued Jones. "ColoMarker is the first 'blood-based' assay that will simplify the whole process for both patients and doctors."

The ColoMarker assay currently tests a serum sample on a microtiter plate ELISA platform.

EDP has applied for patents on the reagents and assay, and is moving toward next steps for the commercialization of the test.

About EDP Biotech

EDP Biotech Corporation is a privately held medical device company focused on the development and sale of immunodiagnostic tests for both humans and animals. EDP utilizes more than 30 years of research and development in identification and purification of proteins present in the early stages of biological changes for production of in vitro diagnostic tests whose primary target is early detection.

*The reported results for the FOB test were lower than seen in other studies. The patients used for the study may have caused this. The false positive rate on FOB for patients referred to a GI specialist is higher than seen for the general population. Even for this problematical patient set, the ColoMarker assay provided significantly better performance.

ColoMarker™ is a trademark of the EDP Biotech Corporation.

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