Published Trial Results Indicate High Sensitivity and Reproducibility of Early Colon Cancer Detection by ColoMarker Blood Test

Knoxville, Tenn. – (August 31, 2015) – EDP Biotech Corporation, (EDP), a global *in vitro* diagnostic innovator of simple, blood-based cancer diagnostic tests, announces the publication of key study data for its ColoMarker® ELISA kit. In this clinical research study, ColoMarker demonstrated an overall sensitivity of 97.7% with specificity of 84.4% for all colorectal cancer detection and a nearly 100% sensitivity for early stage (I, II and III) colorectal cancer. Additionally, ColoMarker demonstrated 40% sensitivity to adenomatous polyps. ColoMarker received CE Mark approval as an aid in the detection of early stage colorectal cancer in late 2014.

The publication entitled *CA 11-19: A Tumor Marker for the Diagnosis of Colorectal Cancer*, is published in the September issue of the *Journal of Gastrointestinal Endoscopy.* Clinical performance of ColoMarker was determined utilizing a cohort of 522 consecutively collected serum samples that were obtained under a multi-center IRB protocol. Blood samples were blinded and clinical status was confirmed with colonoscopy prior to testing. Additionally, reproducibility of ColoMarker was evaluated using blinded, duplicate samples run in two US locations and then analysed.

Adequate sample numbers were obtained to demonstrate overall colorectal cancer sensitivity of 128/131 or 97.7% (CI of 93.1 – 99.5%) and an overall specificity of 275/326 or 84.4% (CI of 80.0 – 87.9%). Further, in early stage cancer, ColoMarker identified 31/31 stage 1 cancers, 32/32 stage 2 cancers and 33/33 stage 3 cancers (CI of 96.0 – 100%). Forty percent of adenomatous polyps were detected (26/65).

According to the CDC, the incidence rate of colon cancer is approximately 57 per 100,000. If ColoMarker were applied to the US population, the odds of detecting colorectal cancer from a positive test would be **six times higher** than if individuals were selected at random. Conversely, those with a negative test are **17 times less likely** to have colorectal cancer than individuals selected at random.

In inter-laboratory testing, high reproducibility was reported between samples and sites having matched 58/61, with 95% agreement. Likewise, both inter- and intra-plate repeatability were high with coefficients of variation of 6.5% and 7.4% respectively.

Finally, no differences were observed in the rate of positivity when assessed by age, race, gender, medication or smoking status.

According to lead author and past president of the American Society of Gastrointestinal Endoscopy, Bergein Overholt, M.D., “these results from ColoMarker testing suggest that CA11-19 is an indicator of early colorectal cancer and that diagnosis of colon cancer

can be strongly suggested by using this simple blood test**”**. According to the CDC, one in 20 people in the US will be diagnosed with colon cancer in their lifetime costing the healthcare system $8.4 billion per year. “This test has the potential to not only detect colorectal cancer at a very high confidence level, but also to detect it at the earliest stages where treatment options are most successful and least costly.”

“EDP is pleased with the positive outcome that ColoMarker has achieved. We believe that the compelling results from this clinical study set a new standard in providing affordable and accessible colon cancer testing for people worldwide. As we begin to commercialize our test next year, we expect that these data will be the foundation for similar outcome studies. We look forward to publishing those trials with our global partners,” said Eric Mayer, CEO of EDP Biotech.

About Colon Cancer

Colon cancer is the third most diagnosed cancer and second leading cause of cancer-related deaths in the US and is expected to cause nearly 50,000 deaths in 2015. However, colon cancer is one of the most treatable cancers and if detected early, the five-year survival rate is nearly 90%. Unfortunately only about 40% of people are diagnosed at this early stage when treatment is most likely to be successful and 1 in 3 people over 50 years of age are not screened at all. Abnormal growths called polyps are very common in the colorectal tract however some can become cancerous over time. While there are currently several options available for cancer screening, people are often not screened due to lack of awareness, the high cost, inconvenience and invasiveness of current testing options.

About EDP Biotech Corporation

EDP Biotech is dedicated to the development and commercialization of innovative cancer diagnostics that are simple, accurate and cost-effective including the ColoMarker® ELISA kit for detection of early stage colorectal cancer. ColoMarker received CE Mark approval as an aid in the detection of early stage colorectal cancer in late 2014 and is not approved for use in the US. For more information on EDP Biotech, visit our websites: www.ColoMarker.com or www.EDPbiotech.com.

Forward-Looking Statements

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements contained in this release that are not historical facts, including, without limitation, statements that relate to the Company's expectations with regard to the future impact on the Company's results from new products in development, may be deemed to be forward-looking statements. Words such as "expects", "intends", "plans", "may", "could", "should", "anticipates", "likely", "believes" and words of similar import also identify forward-looking statements. These statements are subject to risks and uncertainties. Forward-looking statements are based on current facts and analyses and other information that are based on forecasts of future results, estimates of amounts not yet determined and assumptions of management. Readers are urged not to place undue reliance on the forward-looking

statements, which speak only as of the date of this release. Except as may be required under applicable law, we assume no obligation to update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this release.

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