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Press release

Congressman Donald M. Payne, Jr. Introduces Bipartisan 2016 Colorectal Cancer Detection Act

Legislation aims to provide coverage under the Medicare program for FDA-approved qualifying colorectal cancer screening blood-based tests

Berlin (Germany) and Germantown, MD (U.S.A.), September 29, 2016 – Congressman Donald M. Payne, Jr. (D-NJ), today introduced the ''Donald Payne Sr. Colorectal Cancer Detection Act of 2016'' at a panel discussion held in Washington D.C. The bipartisan initiative, led on the Republican side by Congressman Charles Dent (R-PA), aims to provide coverage under the Medicare program for FDA-approved qualifying colorectal cancer (CRC) screening blood-based tests.

"Colorectal cancer is one of the most preventable forms of cancer, yet it remains the second leading cause of cancer death in the United States, mainly because 1 in 3 Americans do not stay up-to-date with their screenings. We need new and innovative tools to reach these patients," said Congressman Donald M. Payne, Jr. "While the Food and Drug Administration has recently approved a new blood-based screening test, which will enable historically underserved communities to more fully participate in screening, the Centers for Medicare & Medicaid Services reimbursement is not yet aligned with it. For this reason, I have introduced legislation that would include all FDA-approved blood-based screening tests with available screening methods and authorize equivalent CMS reimbursement. By doing so, we can finally close the gap and screen the unscreened."

"Making sure that all patients, particularly those from historically underserved areas, take full advantage of early detection and screening is vitally important in the fight to prevent needless deaths from colorectal cancer," said U.S. Rep. Charlie Dent (R-PA). "A person's geography or their economic status should not be the driving factor as to whether they survive colorectal cancer. Our bill, by formalizing CMS payment for FDA approved tests on the market today, will better enable physicians to reach those one in three people who are not screened today."

"We are very excited to join the mission of Congressman Payne, Jr. and Congressman Dent to fight colorectal cancer in the United States," said Greg Hamilton, Chief Executive Offer of Epigenomics AG. "This new initiative is a unique opportunity to provide millions of unscreened, underserved Americans access to colorectal cancer screening and to ultimately save thousands of lives."

The panel entitled "Screening the Unscreened: New Approaches to Reaching the Underserved to Prevent Colorectal Cancer" included leading experts within the Colorectal Cancer and gastroenterology community:

"Death from colorectal cancer is preventable if caught early," said Jeffrey Cossman, M.D., Founder of United States Diagnostic Standards, Inc. (USDS) and Association for Molecular Pathology (AMP). "But despite decades of our best efforts, still 1 in 3 or almost 23 million Americans are not screened. A new, cost-effective DNA blood-test for colorectal cancer screening is a unique opportunity to overcome existing testing barriers and disparities. There is overwhelming evidence that underserved and rural populations suffer most from low colorectal cancer screening rates."

"There is clear evidence that lack of colorectal cancer screening results in a higher incidence of late-stage colorectal cancer disproportionately in ethnic minorities," said Amar R. Deshpande, M.D., Vice Chief for Education, Division of Gastroenterology (Department of Medicine), University of Miami. "A patient

accepted blood test covered under Medicare could benefit these communities and thereby reduce the number of related deaths."

"As a practicing primary care physician, the importance of regular colorectal cancer screening cannot be overemphasized," said Raymond Nungesser, M.D., Family Medicine Practitioner, Geisinger Health System. "Unfortunately, barriers exist for many of my rural patients. A blood test for colorectal cancer screening addresses those barriers and provides medical professionals with a new tool in the fight against one of the deadliest cancers in the United States."

"The advances in molecular diagnostics have provided us with a disruptive technology to reach the 1 in 3 who have avoided colorectal cancer screening," said Nicholas Potter, PhD., Executive Vice-President of Clinical Affairs, Molecular Pathology Laboratory Network. "The introduction of a novel DNA blood test has the potential to increase compliance with colorectal cancer screening, as demonstrated in clinical studies."

"We are extremely pleased by Congressman Donald Payne's colorectal cancer screening initiative," said Michael Sapienza, Chief Executive Officer, The Colon Cancer Alliance. "Improving access to new technologies for colorectal cancer screening will contribute to reaching 80% screening rates by 2018 and to fulfilling our mission of ultimately knocking out colorectal cancer."

About colorectal cancer (CRC)

The American Cancer Society projects there will be over 134,000 new diagnosed cases of colorectal cancer, and almost 50,000 deaths, from colorectal cancer in 2016 in the United States. Colorectal cancer remains the second-leading cause of cancer death in the United States. Although screening and early detection of colorectal cancer can save lives, about 35 percent of eligible U.S. patients are not being regularly screened. While the 5-year survival rate for early colorectal cancer (stage I) is 90%, only four-out-of-ten cases are diagnosed at this early stage. According to the American Cancer Society, this is in part due to the underuse of screening.

About Epi proColon

Epi proColon is indicated for colorectal cancer screening in average-risk patients who are unwilling or unable to perform colorectal cancer screening by colonoscopy and stool-based methods.

For patients, the test only requires a simple blood sample drawn as part of routine healthcare provider visits. There are no dietary restrictions or alterations in medication required for the test. The sample will be analyzed at a national or regional diagnostic laboratory.

Epi proColon is an in-vitro PCR (polymerase chain reaction) assay for the qualitative detection of Septin9 gene methylation in DNA isolated from the patient's plasma. Cytosine residues of the Septin9 gene are methylated in colorectal cancer tissue, but not in normal colon mucosa. This tumor-specific methylation pattern can be used to detect cell-free DNA shed into the blood stream by tumor cells. Detection of colorectal cancer-derived DNA in blood plasma using the Septin9 methylation biomarker was demonstrated in multiple clinical studies, to be a reliable indicator of the presence of colorectal cancer.

Clinical evidence of Epi proColon

Epi proColon received FDA approval based on demonstration of safety and efficacy, as established in clinical studies. The test has also demonstrated its potential to increase participation rates in colorectal cancer screening.

The approval was based on a major clinical validation study with approximately 8,000 individuals at average risk to develop colorectal cancer. In this study, the test detected 68% of all cancer cases at 80% specificity. In a second study, conducted head-to-head against FIT, it was shown that Epi proColon is

statistically non-inferior to FIT in detecting colorectal cancer. Additionally, in the ADMIT (Adherence to Minimally Invasive Testing) trial, it was demonstrated that blood-based testing with Epi proColon has the potential to increase compliance with colorectal cancer screening, compared to FIT stool-based testing. In the ADMIT trial, Epi proColon reached an adherence rate of 99.5% among previously screening resistant participants.

For more information on Epi proColon, visit www.epiprocolon.com.

About Epigenomics

Epigenomics is a molecular diagnostics company focused on blood-based detection of cancers using its proprietary DNA methylation biomarker technology. The company develops and commercializes diagnostic products across multiple cancer indications with high medical need. Epigenomics' lead product, Epi proColon, is a blood-based screening test for the detection of colorectal cancer. Epi proColon has received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in the United States, Europe, and China and selected other countries. Epigenomics' second product, Epi proLung®, is in development as a blood-based test for lung cancer detection.

For more information, visit www.epigenomics.com.

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