



Bio Preventive Medicine Corp. Debuts European CE IVD Approved Diabetic Kidney Disease Preventive Detection Kit “DNIite-IVD103”

Bio Preventive Medicine Corporation (BPM), a leading-edge In Vitro Diagnostics (IVD) company, announced on Feb. 11th, 2020, that their diagnostic kit DNIite-IVD103 has obtained CE IVD mark and is approved for sale in the European Union. This makes DNIite-IVD103 the first globally available diagnostic kit for preventing diabetic kidney disease from progressive decline.

“With the number of diabetes patients worldwide reaching nearly half-a-billion, and 40% of that population developing kidney complications, it has never been more critical to shift from diagnosis to prevention,” said BPM CEO, Dr. Karen Tseng. Currently, the 5-year survival rate of an End Stage Kidney Disease is less than 50% if the disease originated from Diabetic Kidney Disease (DKD). In the US alone, 37 million kidney disease patients incur annual medical expenses of \$114 billion USD on the government. These figures led US President Donald Trump to sign an executive order aiming at improving the testing, diagnosis and treatment of kidney disease for Americans.

DNIite-IVD103 is the first kit that precisely manages DKD. By detecting a specific urinary biomarker and meticulously monitoring for post translational modifications to the marker, DNIite-IVD103 can effectively predict the kidney condition of a diabetes patient over the 1-2 years that follow. If a risk of progressive Glomerular Filtration Rate (GFR) decline is detected, patients can be recommended to start proper treatment earlier, and seize a critical window for clinical action and even recovery. Prediction of decline or kidney complications will drastically improve the DKD patient’s quality of care.

The ingenuity behind BPM’s innovation is developing DNIite-IVD103 as an ELISA (Enzyme Linked Immunosorbent Assay) test with the ability to detect specific Post Translational Modification of a novel DKD biomarker, which was identified in a large-scale profiling of urinary proteomics. DNIite-IVD103 requires fewer steps and shorter processing times, even for high-throughput samples. It effectively overcomes time-consuming and costly obstacles of current advanced biomarker diagnosis that are often detected by proteomics technology, and it also alleviates the concern of low sensitivity in predicting renal function loss found in traditional diagnostic methods. The flexibility of DNIite-IVD103 allows for onsite testing in regular hospitals and diagnostic centers.

On its journey to CE regulatory approval, DNIite platform accumulated clinical data from more than 3,000 patients including a clinical trial sponsored by a global heavyweight pharmaceutical company. Additional studies were completed a national project with the Renal Biomarker Consortium, a Type2 Diabetes project led by Professor Lee-Ming Chuang from Department of Metabolism in National Taiwan University Hospital, a Type 1 Diabetes project led by professor Yann-Jinn Lee hailing from the Pediatrics Department of Mackay Memorial Hospital(MMH), and several cross-national research projects with the Netherlands and Japan.



DNlite-IVD103 has officially obtained CE IVD mark and will first target the European market. According to publications by the International Diabetes Federation (IDF), the potential business opportunity for DKD-related diagnostics in Europe will be more than \$66 million US dollars. Bio Preventive Medicine Corp. will offer DNlite-IVD103 testing through local sales channels for medical institutes and diagnostic laboratories. This will help doctors and diabetes patients develop a disease management plan together and dramatically improve the quality of patients' medical care and life.

Bio Preventive Medicine Corp. will also continue working toward regulatory approval in countries with high risk of DKD such as Taiwan, Malaysia, Singapore, and the United States. For those interested in learning more about DNlite-IVD103 in person, BPM will be exhibiting at the World Congress of Nephrology (WCN) 2020 in Abu Dhabi, UAE from March 26th till the 29th at Booth 19.

About Bio Preventive Medicine (BPM):

Bio Preventive Medicine (BPM) is a leading-edge developer of biomarker solutions and technology. BPM focuses on translating validated and IP-protected novel biomarkers into diagnostic solutions for unmet clinical needs. The company's expertise in Diabetic Kidney Disease (DKD) and non-proteinuric renal disease led to the development of breakthrough technology DNlite-IVD103, the world's first regulatory-approved non-invasive urinary test for predicting the progression of DKD. For more information, please refer to BPM official website: <http://www.bpmbiotech.com/>

Press Release: Feb 11, 2020

Contact: karen.tseng@bpmbiotech.com