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Taiwan firm puts focus on preventing diabetic kidney disease

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“DNlite-IVD103” becomes the first globally available ELISA (Enzyme-linked Immunosorbent Assay) diagnostic kitfor preventing diabetic kidney disease from the progressive decline

Taiwan's Bio Preventive Medicine Corporation (BPM), a leading-edge In Vitro Diagnostics (IVD) company, has announced that their diagnostic kit DNlite-IVD103 has obtained CE IVD mark and is approved for sale in the European Union.

Soon after Europe, DNlite-IVD103 will obtain MDA and HSA approvals from Malaysia and Singapore in 2020 Q3 and enter Southeast Asia market. This makes DNlite-IVD103 the first globally available ELISA (Enzyme-linked Immunosorbent Assay) 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).

DNlite-IVD103 is the first ELISA kit that precisely manages DKD. It 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 DNlite-IVD103 as an ELISA 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. DNlite-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, such as UACR and eGFR. The flexibility of DNlite-IVD103 allows for onsite testing in regular hospitals and diagnostic centers.

DNlite platform has accumulated clinical data from more than 3,000 patients including a phase IIIb clinical trial sponsored by a global heavyweight pharmaceutical company. Additional studies were completed with the Taiwan 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 United States, Malaysia, Singapore, and Taiwan. DNlite-IVD103 will be expected to obtain MDA and HAS premarket approval for Malaysia and Singapore in 2020 Q3. For those interested in learning more about DNlite-IVD103, BPM will be exhibiting at the 56th EASD 2020 virtual exhibition from September 21st till the 25th.