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DiaMedica gets FDA nod to Initiate Clinical Trial of DM199 for CKD

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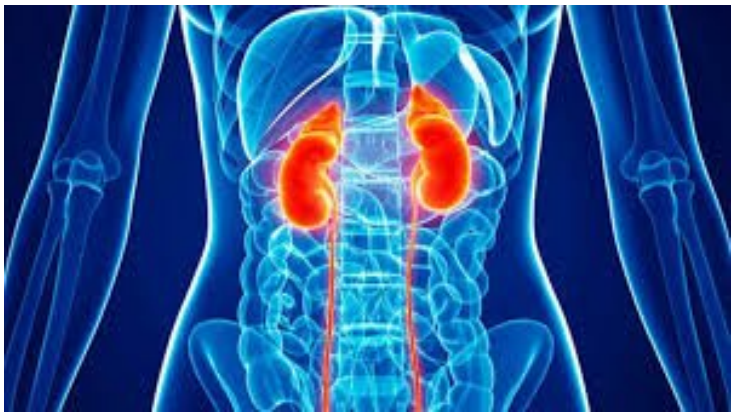

DiaMedica Therapeutics Inc. has announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's Phase II clinical trial protocol for the treatment of Chronic Kidney Disease (CKD). The Phase II trial is designed to assess the safety and efficacy of DM199 in the treatment of CKD in two cohorts: patients with CKD caused by IgA nephropathy (IgAN) and hypertensive African American patients with CKD. DiaMedica intends to initiate participant enrollment in the next few weeks.

"Based upon the Company's previously announced Phase Ib results demonstrating early signals in both estimated glomerular filtration rate (eGFR) and albuminuria improvement, which were consistent with published clinical data using porcine-derived KLK1 in Asia for CKD, we are cautiously optimistic about the potential for DM199 to provide a safe and effective new treatment option for individuals suffering from CKD," said Rick Pauls, DiaMedica's President and CEO. "We are looking forward to working with patients and physicians to evaluate the potential of DM199."

DM199 is a recombinant (synthetic) form of the human serine protease kallikrein (KLK1). The KLK1 protein plays an important role in the regulation of a variety of physiological processes in the kidneys, including blood flow, inflammation, fibrosis and oxidative stress. The Company believes that DM199 may restore KLK1 levels, enabling the natural physiologic process of the body to selectively release bradykinin-mediated nitric oxide, prostaglandins (PGE2 and PGI2-cAMP) and other anti-inflammatory mediators in the kidneys, which in turn may work synergistically to improve renal blood flow (dilating both afferent & efferent arterioles) and reduce inflammation, oxidative stress and fibrosis. The Company also believes that DM199 may play a role in restoring the body's ability to naturally regulate the function of the epithelial sodium channel (ENaC), which controls sodium levels in the body.

This Phase II study is a multi-center, open-label investigation of approximately 60 participants with CKD, who will be enrolled in two cohorts, and will be conducted in the United States at up to 10 sites. The study will be focused on participants with CKD caused by IgAN and non-diabetic, hypertensive African American participants with CKD. African Americans are at greater risk for CKD than Caucasians, and African Americans who have the APOL1 gene mutation are at an even higher risk.

The study is designed to capture APOL1 gene mutation as an exploratory biomarker. The study will evaluate two dose levels

of DM199 within each cohort. Study participants will receive DM199 by subcutaneous injection twice weekly for 95 days. The primary study endpoints include safety, tolerability, blood pressure and kidney function, which will be evaluated by changes from base line in eGFR and albuminuria, as measured by the urinary albumin to creatinine ratio (UACR).