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OPKO Health Completes Acquisition of Two Phase 3 Products

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) announced that it has completed the acquisition of Cytochroma Inc. (Markham, Canada). Cytochroma's lead products include CTAP101 Capsules, a vitamin D prohormone to treat secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency, and Fermagate Tablets, a new and potent non-absorbed phosphate binder to treat hyperphosphatemia in CKD patients on chronic hemodialysis.

CTAP101 Capsules have been shown in a phase 2b clinical trial to effectively and safely treat SHPT and the underlying vitamin D insufficiency in pre-dialysis patients. Vitamin D insufficiency arises in CKD due to the abnormal upregulation of CYP24, an enzyme which destroys vitamin D and its metabolites. Studies in CKD patients have demonstrated that currently available over-the-counter and prescription vitamin D products cannot reliably raise blood vitamin D prohormone levels and effectively treat SHPT. CTAP101 Capsules are in phase 3 clinical trials in the United States (US).

The new phosphate binder, Fermagate Tablets, has been shown to be safe and effective in treating hyperphosphatemia in phase 2 and 3 trials in CKD patients undergoing chronic hemodialysis. Hyperphosphatemia contributes to soft tissue mineralization and affects approximately 90% of dialysis patients. Dialysis patients require ongoing phosphate binder treatment to maintain normal serum phosphorus levels. Opko is working with US and European regulatory authorities to finalize the remaining Phase 3 clinical program for Fermagate Tablets.

About Chronic Kidney Disease

CKD is a condition characterized by progressive decline in renal function. The kidney is normally responsible for excreting waste and excess water from the body and for regulating various hormones. CKD is classified in five stages — mild (stage 1) to severe (stage 5) disease — according to glomerular filtration rate. According to the National Kidney Foundation, CKD afflicts over 26 million people in the US, including more than eight million patients with stage 3 or 4 CKD. In stage 5, kidney function is minimal to absent and patients require regular dialysis or a kidney transplant for survival.

About Vitamin D Insufficiency

Vitamin D insufficiency is a condition in which blood levels of vitamin D prohormones, collectively known as 25-hydroxyvitamin D, are inadequate. An estimated 70-90% of CKD patients have vitamin D insufficiency which can lead to SHPT and its debilitating consequences.

About Secondary Hyperparathyroidism (SHPT)

SHPT is a condition commonly associated with CKD in which the parathyroid glands secrete excessive amounts of parathyroid hormone (PTH). SHPT arises as a result of vitamin D insufficiency or impaired kidney function. Prolonged elevation of blood PTH causes excessive calcium and phosphorus to be released from bone, leading to elevated serum calcium and phosphorus levels, softening of the bones (osteomalacia) and calcification of vascular and renal tissues. SHPT affects 40-60% of patients with stage 3 or 4 CKD and approximately 90% of patients with stage 5.

About Hyperphosphatemia

Hyperphosphatemia, or elevated serum phosphorus, is common in dialysis patients and tightly linked to the progression of SHPT. The kidneys provide the primary route of excretion for excess phosphorus absorbed from ingested food. As kidney function worsens, serum phosphorus levels increase and directly stimulate PTH secretion. Stage 5 CKD patients must reduce their dietary phosphate intake and usually require regular treatment with phosphate binding agents to lower serum phosphorus to meet the recommendations of the National Kidney Foundation's Clinical Practice Guidelines that serum phosphorus levels should be maintained at or below 5.5 mg/dL.

About OPKO Health, Inc.

We are a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies.

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding the benefits and synergies resulting from the acquisition of Cytochroma, including whether the Phase 3 clinical trials for CTAP101 Capsules and Fermagate Tablets may be completed on a timely basis or at all, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that any of CTAP101 Capsules, Fermagate Tablets and/or any of our compounds or diagnostics under development, including our point-of-care vitamin D diagnostic test may fail, may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of products for the indications being studied or for other indications, that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than Cytochroma's products for the indications being studied, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described in our filings with the Securities and Exchange Commission, as well as that the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments may not be met. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and

indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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