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OPKO Health to Acquire Two Phase 3 Products

New Vitamin D Prohormone and Phosphate Binder for Kidney Disease Patients

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) has entered into a definitive agreement to acquire Cytochroma Inc. (Markham, Canada) whose lead products, both in phase 3 clinical trials, are Replidea™ (coded 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 Alpharen™, a non-absorbed phosphate binder to treat hyperphosphatemia in dialysis patients.

Replidea™ has 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 or effectively treat SHPT.

“OPKO intends to market Replidea™ along with our proprietary point-of-care vitamin D diagnostic test currently in development,” stated Phillip Frost, MD, CEO and Chairman. “We envision these remarkable products as part of the foundation for a new and markedly improved standard of care for chronic kidney disease patients having SHPT and/or hyperphosphatemia.”

Alpharen™ has been shown safe and effective in treating hyperphosphatemia in the phase 2 and 3 clinical trials undertaken to date in dialysis patients. Hyperphosphatemia (elevated serum phosphorus) exacerbates SHPT and promotes bone disease, soft tissue mineralization and progression of kidney disease. Approximately 90% of dialysis patients in the United States require regular treatment.

Cytochroma’s officers, including Charles W. Bishop, PhD, CEO, an authority on developing and commercializing successful new vitamin D therapies, and Eric J. Messner, MBA, having a noteworthy track record in pharmaceutical business development and in marketing and sales in the CKD arena, will join the OPKO management team. Prior to Cytochroma, Dr. Bishop and Mr. Messner held key positions at Bone Care International, Inc., a leader in vitamin D therapeutics acquired by Genzyme Corporation, now a division of Sanofi.

About Chronic Kidney Disease

CKD is a condition characterized by a progressive decline in kidney 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 different stages – mild (stage 1) to severe (stage 5) disease – as measured by the kidney’s 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 and 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 and 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 <5.5 mg/dL.

About OPKO Health, Inc.

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise and 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 Replidea™ and Alpharen™ 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 Replidea™, Alpharen™ 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, that the various conditions to the closing of the transaction with Cytochroma may not be met, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. 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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