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OPKO Health Announces Key Executive Appointments for Renal Division

- **Scott Toner Joins as Vice President, US Marketing and Sales**
- **Stephen A. Strugnell Joins as Senior Director, Scientific Affairs**

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced the hiring of key executives for its Renal Division. Scott Toner will join as Vice President, US Marketing and Sales and Dr. Steve Strugnell will join as Senior Director, Scientific Affairs.

Mr. Toner has over 30 years of pharmaceutical experience with a history of developing effective marketing strategies for new drugs to treat chronic kidney disease (CKD). Mr. Toner was previously Senior Director of Global Marketing at Reata Pharmaceuticals with responsibility for the marketing strategy supporting a new innovative therapy for CKD in type 2 diabetes patients; Executive Director of Marketing at AMAG Pharmaceuticals where he led the launch of Feraheme®, an iron replacement product for dialysis patients; and Director of Renal Commercial Development at Abbott Laboratories with responsibility for Zemplar®. Zemplar became the most successful vitamin D therapy for secondary hyperparathyroidism (SHPT) in the US. Mr. Toner also serves as a member of the Board of the American Association of Kidney Disease Patients (AAKP).

Dr. Strugnell has extensive experience in the research and development of new vitamin D drugs for CKD patients with vitamin D insufficiency. Prior to OPKO, he was Associate Scientific Director at Genzyme Renal and Associate Director of Preclinical Research at Bone Care International where he managed research supporting Hectorol®, the first modern vitamin D product approved in the US for SHPT in pre-dialysis patients. Dr. Strugnell received his PhD degree from Queens University under the direction of Dr. Glenville Jones, and completed a post-doctoral fellowship at the University of Wisconsin-Madison under the direction of Dr. Hector DeLuca. Drs. Jones and DeLuca are internationally regarded experts on vitamin D metabolism.

"Scott and Steve are powerful additions to our management team," said Dr. Charles W. Bishop, CEO of OPKO Renal. "These two individuals have a remarkable understanding of the renal market and provide unparalleled experience in developing and launching proprietary renal disease products."

“The hiring of Scott as Vice President, Marketing and Sales and Steve as Senior Director, Scientific Affairs is an important milestone as we continue to develop our pipeline of renal products and prepare for the commercial launch of Rayaldee™ to treat CKD patients,” said Phillip Frost, M.D., Chairman and CEO of OPKO. “We are pleased to welcome Scott and Steve.”

About Rayaldee™

Rayaldee is a first-in-class oral vitamin D prohormone treatment being developed for SHPT in stage 3 and 4 CKD patients with vitamin D insufficiency. It has a proprietary modified-release formulation designed to gradually and reliably raise serum total 25-hydroxyvitamin D (prohormone) concentrations to targeted levels (at least 30 ng/mL) while avoiding upregulation of CYP24, a cytochrome P-450 enzyme that reduces the parathyroid hormone (PTH) lowering potency of current vitamin D supplements. Activation of calcifediol, the active ingredient in Rayaldee, by the kidney is tightly regulated, preventing excessive elevation of serum calcium and related side effects which encumber current vitamin D hormone therapies and promote vascular and renal calcification. Once approved, Rayaldee is expected to address the approximately 4 million CKD stage 3 and 4 patients in the US and many more, elsewhere, with SHPT and vitamin D insufficiency.

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 moderate (stages 3 and 4) and severe (stage 5) forms of CKD. In stage 5 CKD, 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 the body has low vitamin D stores, characterized by inadequate blood levels of vitamin D prohormone, known as 25-hydroxyvitamin D. An estimated 70-90% of CKD patients have vitamin D insufficiency, which can lead to SHPT and resultant debilitating bone diseases.

About Secondary Hyperparathyroidism (SHPT)

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

About OPKO

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), regarding product development efforts and other non-historical facts about our expectations, beliefs or intentions regarding

our business, technologies and products, financial condition, strategies or prospects, including statements regarding our ability to successfully launch and commercialize proprietary renal disease products, expectations about Rayaldee™, its market potential, that it will address the approximately 4 million CKD stage 3 and 4 patients in the US and many more elsewhere, with SHPT and vitamin D insufficiency, and that we will be able to successfully develop, obtain approval for and launch sales of Rayaldee™. 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 risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, including the risks that the phase 3 clinical trials for Rayaldee™ may not be successful or achieve the expected results or effectiveness, and may not generate data that would support the approval or marketing of this product for the indications being studied, that others may develop products which are superior to Rayaldee™, and that Rayaldee™ may not have advantages or prove to be superior over presently marketed products, including the currently used high monthly doses of prescription vitamin D_2, activated vitamin D hormone and over-the-counter vitamin D supplements. 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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