November 5, 2015

Additional Phase 3 Data Supporting OPKO's Rayaldee as a Treatment for Secondary Hyperparathyroidism in Chronic Kidney Disease to be Presented at Kidney Week 2015

MIAMI--(BUSINESS WIRE)-- **OPKO Health, Inc. (NYSE: OPK)**, a multinational biopharmaceutical and diagnostics company, announces that additional Phase 3 data on Rayaldee™ as a treatment for secondary hyperparathyroidism (SHPT) will be highlighted later today in a poster presentation at Kidney Week 2015, the Annual Meeting of the American Society of Nephrology (ASN) underway in San Diego, California. The data showed that plasma levels of intact parathyroid hormone (iPTH) continued to fall as serum levels of 25-hydroxyvitamin D (25D) rose above 30 ng/mL, a level considered sufficient for CKD patients in published clinical practice guidelines. These data suggest that patients with stage 3 or 4 CKD require higher levels of serum 25D than previously thought in order to control elevated iPTH.

OPKO's poster presentation entitled "Efficacy and Safety of Modified-Release Calcifediol in Stage 3-4 CKD Patients with Secondary Hyperparathyroidism and Vitamin D Insufficiency," will be presented by lead author Stuart M. Sprague, DO, Chief, Division of Nephrology and Hypertension, NorthShore University Health System - University of Chicago, Pritzker School of Medicine.

Session details

Date:	Thursday, November 5
Time:	10:00 a.m. – 12:00 p.m. Pacific time
Location:	San Diego Convention Center, Hall B
Poster:	#TH-PO641

About Rayaldee

Rayaldee (calcifediol modified-release capsules) is an oral vitamin D prohormone treatment being developed for SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency. It has a proprietary modified-release formulation designed to gradually raise serum total 25-hydroxyvitamin D (prohormone) concentrations to targeted levels (at least 30 ng/mL) while avoiding upregulation of CYP24A1, a cytochrome P-450 enzyme which interferes with the desired parathyroid hormone (PTH)-lowering effect. Gradual elevation of serum total 25-hydroxyvitamin D is intended to prevent excessive elevation of serum calcium and related

vascular and renal calcification.

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 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 U.S., including more than 20 million patients with moderate (stages 3 or 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. Vitamin D insufficiency has been associated with increased mortality in CKD.

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 Health, Inc.

OPKO Health, Inc. is a diversified healthcare company that seeks to establish industry-leading positions in large, rapidly growing markets. Our diagnostics business includes Bio-Reference Laboratories, the nation’s third-largest clinical laboratory with a core genetic testing business and a 420-person sales force to drive growth and leverage new products, including the 4Kscore® prostate cancer test and the Claros®1 in-office immunoassay platform. Our pharmaceutical business features Rayaldee™, a treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency (March 29, 2016 PDUFA date) and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation approved by FDA and pending launch by partner Tesaro, IV formulation in Phase 3). Our biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a long-acting Factor VIIa drug for hemophilia (entering Phase 2a). We also have production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is available at www.opko.com.

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 the expected PDFUA date and whether Rayaldee will be approved by the FDA, our ability to successfully launch and commercialize Rayaldee, expectations about Rayaldee, that Rayaldee will effectively control secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease by correcting vitamin D insufficiency, whether Rayaldee is appropriate for patients with minimal functioning kidney mass and its efficacy during longer term administration, whether Rayaldee will be highly effective in correcting vitamin D insufficiency, allowing more reliable treatment of patients, market potential for Rayaldee, 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 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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