

February 7, 2017



## OPKO Health Promotes Thomas Nusbickel to Renal Division Chief Commercial Officer

*Enhances leadership for RAYALDEE® with deep industry knowledge in nephrology; refocuses commercial structure on field representatives*

MIAMI, Feb. 07, 2017 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) announced the promotion of Thomas Nusbickel to the newly created position of Chief Commercial Officer of OPKO Health's Renal Division, effective immediately. In this new role, Mr. Nusbickel will lead the continued commercialization of RAYALDEE® (calcifediol) extended-release capsules for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency. Mr. Nusbickel, previously Senior Vice President of Marketing and Market Access, will be responsible for all commercial activities, including sales, marketing and market access.

Mr. Nusbickel has 30 years of commercial biopharmaceutical experience leading launches for specialty products at Abbott Laboratories, Amgen, Hospira and Pfizer. Prior to joining OPKO Health last year, Mr. Nusbickel was Head of U.S. Market Access, Biosimilars for Hospira, a Pfizer company, where he built an industry-leading account sales and market access team to support product launches. Mr. Nusbickel gained deep experience in the nephrology market at Amgen, where he led the successful global launch of Sensipar and secured access and reimbursement for Aranesp and Epogen. He is recognized for his ability to develop and implement high-impact product marketing, value messages and strategies to engage payers and marketing organizations to support product launches and life cycle management.

"We are delighted to promote Tom to Chief Commercial Officer as he has a proven record of successfully launching biopharmaceutical products, including within the nephrology market. Tom's duties will include ensuring that all sales, marketing and market access activities are aligned to meet our strategic commercial objectives. He has done an outstanding job in leading our team since RAYALDEE's launch in late November 2016, and he will continue to play a central role as we expand RAYALDEE's market reach to bring this novel therapeutic to the benefit of patients suffering with CKD," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO Health.

Separately, OPKO announced the discontinuation of a 20-person internal telemarketing sales team supporting RAYALDEE. Going forward, the company will use only field-based representatives to promote sales of RAYALDEE within the nephrology community.

### **About RAYALDEE**

RAYALDEE (calcifediol) extended-release capsules are approved by the U.S. Food and Drug Administration (FDA) for the treatment of SHPT in adult patients with stage 3 or 4 CKD and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. RAYALDEE is not indicated for the treatment of SHPT in patients with stage 5 CKD or end-stage renal disease on

dialysis. RAYALDEE has a patented formulation and is designed to raise serum total 25-hydroxyvitamin D (prohormone) concentrations to targeted levels (at least 30 ng/mL) and to reduce elevated intact parathyroid hormone (PTH). The full prescribing information for RAYALDEE is available at [www.rayaldee.com](http://www.rayaldee.com).

Potential side effects of RAYALDEE include hypercalcemia (elevated serum calcium), which can also lead to digitalis toxicity, and adynamic bone disease with subsequent increased risk of fractures if intact PTH levels are suppressed by RAYALDEE to abnormally low levels.

Severe hypercalcemia may require emergency attention; symptoms of hypercalcemia may include feeling tired, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination, and weight loss. Digitalis toxicity can be potentiated by hypercalcemia of any cause. Excessive administration of RAYALDEE can cause hypercalciuria, hypercalcemia, hyperphosphatemia, or oversuppression of iPTH. Common symptoms of vitamin D overdosage may include constipation, decreased appetite, dehydration, fatigue, irritability, muscle weakness, or vomiting. Patients concomitantly taking cytochrome P450 inhibitors, thiazides, cholestyramine, phenobarbital or other anticonvulsants may require dose adjustments and more frequent monitoring.

The most common adverse reactions in clinical trials ( $\geq 3\%$  and more frequent than placebo) were anemia, nasopharyngitis, increased blood creatinine, dyspnea, cough, congestive heart failure and constipation.

### **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. RAYALDEE is only indicated for treating SHPT in patients with stage 3 or stage 4 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 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 OPKO Health, Inc.**

OPKO Health 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, an FDA-approved treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency (launched in November 2016), VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO and IV formulation pending FDA approval), TT401, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and TT701, an androgen receptor modulator for androgen deficiency indications. Our biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in phase 3 and partnered with Pfizer), a long-acting Factor VIIa drug for hemophilia (in phase 2a) and a long-acting oxyntomodulin for diabetes and obesity (in phase 1). 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](http://www.opko.com).

## **SAFE HARBOR STATEMENT**

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 commercialization of RAYALDEE, expected benefits of RAYALDEE, whether we will meet our strategic commercial objectives, whether RAYALDEE will be a successful commercial product, and whether we will expand RAYALDEE's reach to benefit patients suffering with SHPT or CKD, 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 the 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.

## **Contacts:**

OPKO Health, Inc.

David Malina, 305-575-4137  
Investor Relations

or

Media

Rooney & Associates

Terry Rooney, 212-223-0689

[trooney@rooneyco.com](mailto:trooney@rooneyco.com)

or

Marion Janic, 212-223-4017

[mjanic@rooneyco.com](mailto:mjanic@rooneyco.com)

or

Investors

LHA

Anne Marie Fields, 212-838-3777

[afields@lhai.com](mailto:afields@lhai.com)

or

Bruce Voss, 310-691-7100

[bvoss@lhai.com](mailto:bvoss@lhai.com)



Source: OPKO Health Inc.