November 17, 2016

OPKO Presents Data on RAYALDEE® at ASN Kidney Week 2016

MIAMI, Nov. 17, 2016 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (Nasdaq:OPK), announced that data on RAYALDEE (calcifediol) extended-release capsules as a treatment for secondary hyperparathyroidism (SHPT) in stage 3 and 4 chronic kidney disease patients with vitamin D insufficiency will be presented later today in a poster presentation at the American Society of Nephrology Kidney Week Meeting, underway in Chicago, IL.

The data showed that RAYALDEE has similar effectiveness and safety in controlling SHPT in both African-American (AA) and non-African-American (nAA) patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency (defined as serum total 25-hydroxyvitamin D levels less than 30 ng/mL). Serum total 25-hyrdroxyvitamin D levels showed a similar increase in both patient populations beyond the target of 30 ng/mL, a level considered sufficient for CKD patients in published clinical practice guidelines, despite the well established tendency for lower levels in AA patients. Plasma intact parathyroid hormone (iPTH) levels were effectively suppressed by RAYALDEE in AA patients and nAA patients versus placebo treatment.

OPKO's poster presentation entitled "Extended-release Calcifediol is Effective in African-American and Non-African-American Patients with Stage 3-4 CKD, Secondary Hyperparathyroidism and Vitamin D Insufficiency," will be presented by senior 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 17, 2016
Time:	10:00 a.m. – noon Central time
Location:	Exhibit Hall, McCormick Place Convention Center
Poster Board:	512
Abstract Link:	http://www.abstracts2view.com/asn_2016/view.php?nu=5118&type=abstract

About RAYALDEE

RAYALDEE (calcifediol) extended-release capsules is 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 secondary hyperparathyroidism in patients with stage 5 chronic kidney disease 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 iPTH. OPKO expects to launch RAYALDEE in the U.S. through its dedicated renal sales force in November 2016. The full prescribing information for RAYALDEE is available at 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 (≥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 iPTH. 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, VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO and IV formulation PDUFA date: January 2017), 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.

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 RAYALDEE, expectations about RAYALDEE, that RAYALDEE will effectively control secondary hyperparathyroidism in patients with stage 3 or 4 chronic kidney disease, whether RAYALDEE will be safe and effective in controlling SHPT in both African-American and non-African American patients, market potential for RAYALDEE, and the timing for launch 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 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 D2, 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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