

June 5, 2017



## OPKO Health Provides Commercial Update for RAYALDEE

- Approximately 68% of all insured lives now have access to *RAYALDEE*
- On track to reach 75% of insured lives by year end
- Increase to 70 field based nephrology sales representatives underway

MIAMI, June 05, 2017 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ:OPK) announces it has entered into agreements with several large Medicare Part D plan sponsors, including the largest Medicare Part D plan, and additional commercial insurance plans for reimbursement of *RAYALDEE*® (extended-release calcifediol), which expands the percentage of insured lives with access to *RAYALDEE* to approximately 68% as of June 1, 2017.

OPKO's plans for expansion to 70 field based nephrology sales representatives is proceeding by expanding in selective geographic areas as reimbursement coverage is secured. More extensive formulary coverage across Medicare Part D and commercial plans and the larger sales force will support continuing growth of *RAYALDEE* and provide greater access for adults with secondary hyperparathyroidism (SHPT), with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency.

*RAYALDEE* is an extended-release prohormone of the active form of vitamin D3 that is the first and only such therapy approved by the U.S. Food and Drug Administration (FDA) that both raises 25-hydroxyvitamin D and lowers intact parathyroid hormone (iPTH) levels with a safety profile similar to placebo.<sup>1</sup> *RAYALDEE* is indicated for the treatment of SHPT in adults with stage 3 or 4 chronic kidney disease (CKD) and serum total 25-hydroxyvitamin D less than 30 ng/mL.

"We are particularly pleased to have *RAYALDEE* covered by an increasing number of Medicare Part D plan sponsors as a large percentage of SHPT patients with CKD Stage 3 or 4 are Medicare beneficiaries. The additional coverage recognizes the potential benefits of *RAYALDEE* in this patient population and should enhance our commercial efforts as we seek to fill the treatment void for this large unmet medical need," noted Phillip Frost, MD Chairman and CEO of OPKO.

### **About *RAYALDEE***

*RAYALDEE* is indicated for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and serum total 25-hydroxyvitamin D less than 30 ng/mL. It is not indicated in patients with stage 5 chronic kidney disease or end-stage renal disease on dialysis.<sup>2</sup> 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 over-suppression of intact PTH. Common symptoms of vitamin D over-dosage 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 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 400-person sales and marketing team 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), OPK88003, 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, OPK88004, a SARM (Selective Androgen Receptor Modulator) for treating BPH (Benign Prostatic Hypertrophy), OPK88002, a NK-1 antagonist to treat pruritus (itching) in dialysis patients, and OPK88001, a proprietary oligonucleotide to treat Dravet Syndrome. In addition, the Company is advancing its CTP technology, which includes long acting 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 in phase 2a. OPKO also has production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information available at [www.opko.com](http://www.opko.com).

<sup>1</sup> Sprague SM, Crawford PW, Melnick JZ, et al. Use of extended-release calcifediol to treat secondary hyperparathyroidism in stages 3 and 4 chronic kidney disease. *Am J Nephrol*. 2016;44:316-325.

<sup>2</sup> *RAYALDEE* [prescribing information]. Miami, FL: OPKO Pharmaceuticals, LLC; July 2016.

### **Cautionary Statement Regarding Forward-Looking Statements**

*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 of RAYALDEE, our expectations about sales of RAYALDEE and continued growth in sales, whether we will obtain broad formulary status across Part D and commercial plans and increase the number of sales representatives to support continuing growth of RAYALDEE and provide greater access for adults with SHPT,*

*and whether RAYALDEE will fill the treatment void for this large unmet medical need, 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 Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and in our other filings with the Securities and Exchange Commission. 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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Source: OPKO Health Inc.