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New Clinical Data on OPKO Health's RAYALDEE® (ER Calcifediol) Presented at Kidney Week 2023

MIAMI, Nov. 02, 2023 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ: OPK) presented late-breaking clinical data on RAYALDEE® extended-release calcifediol (ERC) at the American Society of Nephrology (ASN) Kidney Week in Philadelphia today. These data, presented in a poster titled "Control of Secondary Hyperparathyroidism with Extended-release Calcifediol is Associated with Slower CKD Progression" (#TH-PO1152), indicate that early, sustained and effective treatment of secondary hyperparathyroidism (SHPT) with RAYALDEE is associated with significantly slower progression of chronic kidney disease (CKD) in pre-dialysis patients.

The poster is available on OPKO's website here.

Progressive changes in estimated glomerular filtration rate (eGFR) were examined post-hoc in 166 patients with vitamin D insufficiency, SHPT and stage 3 or 4 CKD during one year of treatment with RAYALDEE in pivotal trials. The average eGFR decline was 7.7% per year but differed significantly and proportionately with the achieved duration of intact parathyroid hormone (iPTH) control, defined as ≤100 pg/mL, being greatest (16.4%) in patients who never achieved control and least (1.7%) in those achieving consistent control. The number of patients experiencing an increase in eGFR by the end of treatment rose from 3.6% to 10.8% as the duration of iPTH control increased. Treatment with RAYALDEE was not associated with clinically meaningful increases in serum calcium or phosphorus.

"Secondary hyperparathyroidism is associated with more rapid CKD progression and earlier dialysis, but mitigation of disease progression by effective control of SHPT has not been previously examined," stated Charles W. Bishop, Ph.D., CEO of OPKO Health's Renal Division. "RAYALDEE is a safe and highly effective treatment for SHPT in patients with stage 3 or 4 CKD. The new data presented today clearly highlight the possibility that raising serum 25-hydroxyvitamin D to a sufficiently high level to achieve consistent iPTH control with RAYALDEE would improve outcomes in CKD patients."

About RAYALDEE®

RAYALDEE is an extended-release (ER) oral formulation of calcifediol, a prohormone of calcitriol, the active form of vitamin D_3. The product is the first and only medicine approved by the U.S. Food and Drug Administration for raising serum total 25D and lowering blood levels of intact parathyroid hormone (iPTH). RAYALDEE is approved to treat SHPT in adults with stage 3 or 4 CKD and vitamin D insufficiency in the U.S. and in 11 European countries. Slowing CKD progression with RAYALDEE treatment is not currently an approved indication.

About OPKO Health, Inc.

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. For more information, visit www.opko.com.

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," “could,” "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding the market for RAYALDEE, and our strategies or prospects and expectations about RAYALDEE, the therapeutic benefits, safety profile or effectiveness of RAYALDEE or whether early initiation of SHPT treatment with RAYALDEE would delay disease progression. 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, as well as the risks that the accuracy and effectiveness of the data may not be reproducible or indicative of future results and that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied. 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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