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# OPKO Health to Present New Clinical Data on Rayaldee (ER Calcifediol) at Kidney Week 2023

MIAMI, Oct. 25, 2023 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ: OPK) will present late-breaking clinical data on RAYALDEE® extended-release calcifediol (ERC) at the American Society of Nephrology (ASN) Kidney Week in Philadelphia on Thursday, November 2, 2023. These data will be presented in a poster, "Control of Secondary Hyperparathyroidism with Extended-release Calcifediol is Associated with Slower CKD Progression" (#TH-PO1152) at 10:00 a.m. Eastern time in Exhibit Halls B-D by authors Charles W. Bishop Ph.D., Stephen A. Strugnell Ph.D. and Akhtar Ashfaq, M.D., FACP, FASN.

OPKO Health will present two other posters at ASN Kidney Week summarizing additional new clinical data on RAYALDEE. One poster, "Extended-release Calcifediol Overcomes Impact of Low eGFR on Vitamin D Metabolism" (#FR-PO319), will be presented in the "Bone and Mineral Metabolism: Basic" session at 10:00 a.m. Eastern time on Friday, November 3, 2023, in Exhibit Halls B-D. The data demonstrate that RAYALDEE effectively and reliably raises serum levels of 25-hydroxyvitamin D (25D) and 1,25-dihydroxyvitamin D in non-dialysis patients with secondary hyperparathyroidism (SHPT), making it an attractive alternative to vitamin D hormone therapies (i.e., calcitriol, paricalcitol and doxercalciferol).

The other poster, "Extended-Release Calcifediol: A Data Journey from Phase 3 Studies to Real-World Evidence Highlights the Importance of Early Treatment of Secondary Hyperparathyroidism" (#FR-PO972), will be presented in the "CKD Interventions: Trials and Quality Improvement" session at 10:00 a.m. Eastern time on Friday, November 3, 2023 in Exhibit Halls B-D. The data demonstrate that effective control of SHPT has been achieved with RAYALDEE treatment in both randomized clinical trials and in a real-world clinical experience trial. Data from these trials support early initiation of SHPT treatment with RAYALDEE in order to delay disease progression.

## About RAYALDEE®

RAYALDEE is an extended-release (ER) oral formulation of calcifediol, a prohormone of calcitriol, the active form of vitamin D<sub>3</sub>. 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](http://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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