

February 3, 2022



RAYALDEE® Launched in Germany by OPKO Health's Licensee, VFMCRP

MIAMI, Feb. 03, 2022 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** announces that Vifor Fresenius Medical Care Renal Pharma (VFMCRP) has initiated the commercial launch of RAYALDEE® (extended release calcifediol) in Germany, the first launch of RAYALDEE outside the U.S. VFMCRP is OPKO's commercial partner for RAYALDEE in Europe and selected markets outside the U.S., and the sales kick-off in Germany began with presentations by VFMCRP executives and several nephrology key opinion leaders.

RAYALDEE extended-release capsules are indicated for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency. VFMCRP has received marketing authorizations for RAYALDEE in 11 European countries and expects to launch in additional markets later this year.

"The launch of RAYALDEE in Germany is a significant commercial milestone with more European countries expected to come on board, beginning with Switzerland in early March. Europe represents a large market opportunity for RAYALDEE with an estimated 26 million people suffering from stage 3 or 4 CKD," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "VFMCRP has significant expertise in nephrology and we are confident in their ability to market RAYALDEE successfully in Germany and other licensed territories."

About RAYALDEE

RAYALDEE is an extended-release oral formulation of calcifediol, a prohormone of calcitriol, the active form of vitamin D₃. 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. It is in development for patients with stage 5 CKD on dialysis.

About Vifor Fresenius Medical Care Renal Pharma

Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care) is part of the Vifor Pharma Group, a global pharmaceutical company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor

Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348). For more information, please visit viforpharma.com.

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, our strategies or prospects and expectations about RAYALDEE and the success of the launch, whether we will be successful in achieving the adoption of RAYALDEE in Germany and the European Countries where we have received marketing authorizations, whether we will launch in those countries, and whether our commercial partner will be successful in its efforts to market 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 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 earlier clinical results of effectiveness and safety 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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