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# OPKO Health Reports Transfer of Licensed Rights to RAYALDEE® in Japan to Vifor

MIAMI, May 24, 2021 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ: OPK) today announced a transfer of the licensed rights to RAYALDEE® in Japan from Japan Tobacco Inc. (JT) to Vifor Fresenius Medical Care Renal Pharma (VFMCRP).

On May 17, 2021, JT notified OPKO of its decision to terminate the exclusive agreement with OPKO's subsidiary, EirGen Pharma, Ltd., for the development and commercialization of RAYALDEE® in Japan based on a comprehensive review of its development pipeline.

Concurrently with the termination of JT's rights, EirGen and VFMCRP have agreed to transfer the rights to RAYALDEE® in Japan to VFMCRP by including Japan into the existing exclusive agreement between the two companies, executed on May 9, 2016, for the development and commercialization of RAYALDEE® in Europe and certain other international markets for the treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) and vitamin D insufficiency.

## About RAYALDEE®

RAYALDEE® is an extended release formulation of calcifediol, a prohormone of calcitriol, the active form of vitamin D<sub>3</sub>. The product is the only medicine approved by the U.S. Food and Drug Administration that sufficiently raises serum total 25-hydroxyvitamin D to effectively lower blood levels of intact parathyroid hormone. RAYALDEE® is approved to treat SHPT in adults with stage 3 or 4 CKD and vitamin D insufficiency in the U.S. and 11 European countries. It is not yet approved 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 (VPG), a global pharmaceutical company. VPG 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. VPG 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 and holds a leading position in all its core business activities. VPG is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).

## 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," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including information about RAYALDEE® and its potential benefits. Risks and uncertainties include, among other things, the uncertainties inherent in VFMCRP's ability to successfully commercialize RAYALDEE® and the success of our relationship with our commercial partners for 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 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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