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OPKO Health to Develop and Commercialize RAYALDEE® in Greater China with Nicoya Therapeutics

MIAMI, June 21, 2021 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** today announced that its subsidiary EirGen Pharma has entered into an agreement with Nicoya Macau Limited, an affiliate of Nicoya Therapeutics (Nicoya), for the development and commercialization in Greater China (mainland China, Hong Kong, Macau and Taiwan) of RAYALDEE® for the treatment of secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD). Nicoya is a leading biotechnology company incubated by 6 Dimensions Capital and its successor fund 120 Capital and other co-investors, and is focusing on the Greater China nephrology market.

Nicoya will make an upfront payment to OPKO of $5 million and an additional $5 million payment will be made during the first 12 months of the agreement or upon Nicoya achieving a certain predetermined development milestone. In addition, OPKO will be eligible to receive up to $115 million upon the achievement of certain development, regulatory and sales-based milestones. Nicoya will also pay OPKO tiered, double-digit royalties on product sales. Nicoya will be responsible for regulatory approvals and commercial activities pertaining to RAYALDEE in their territory.

“We are delighted to work with Nicoya to expand the market for RAYALDEE by establishing a framework for access by physicians and patients across Greater China,” said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. “China represents a significant market opportunity with an estimated 19 million people suffering from stage 3 or 4 CKD. Given Nicoya’s expertise and established network, we are confident this collaboration will provide an effective strategy for RAYALDEE to penetrate this significant and growing market.”

“We recognize the unique value RAYALDEE can bring to CKD patients and want to work together with OPKO to bring this innovative solution to patients in Greater China with unmet medical need related to their kidney health. The OPKO portfolio and strategic focus is fully aligned with Nicoya’s vision to become the leading nephrology platform company in Greater China. We are truly excited about this opportunity,” said Gan Ding, CEO of Nicoya Therapeutics.

RAYALDEE is an extended-release formulation of calcifediol, a prohormone of calcitriol, the active form of vitamin D_3. 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, approved to treat SHPT in adults with stage 3 or 4 CKD and vitamin D insufficiency, was launched in the U.S. in November 2016.

About Nicoya Therapeutics

Nicoya Therapeutics group is a renal-focused biopharma company based in China. Led by a market-leading management team, Nicoya has capabilities spanning from research and development to clinical trial execution to marketing and sales of in-licensed and wholly owned products. Nicoya Therapeutics is incubated by 6 Dimensions Capital and its successor fund 120 Capital, a group of cross-border leading investment funds in the healthcare industry. Other co-investors in Nicoya include Mubadala Investment Company and Beijing Guokonghuayao Investment. Among 6 Dimensions Capital's incubated platform companies in China are Innovent (HKEX:1801), CStone Pharmaceuticals (HKEX: 2616), Ocumension (HKEX:1477, The leading China ophthalmology platform) and Cutia Therapeutics (China's leading dermatology platform).

About OPKO Health

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," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding product development efforts as well as other non-historical statements about our expectations, products, beliefs or intentions regarding our business, financial condition, strategies or prospects including statements regarding expectations about RAYALDEE and the success of the collaboration and licensing agreement with Nicoya, whether Nicoya will successfully develop, obtain regulatory approval for, launch or commercialize RAYALDEE in China, Hong Kong, Macau and Taiwan *whether the parties will successfully develop RAYALDEE for the treatment of SHPT in dialysis patients, whether we will be successful in accelerating adoption of RAYALDEE in China,* Hong Kong, Macau and Taiwan *whether payment milestones and royalty obligations will ever be triggered, and the expected market 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 under the heading "Risk Factors" in our other filings with the Securities and Exchange Commission as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable products and treatments, including the risks that others may develop products which are superior to RAYALDEE, and that RAYALDEE may not have advantages or prove to be superior over presently marketed products, including the currently used high monthly doses of prescription vitamin D_2, activated vitamin D hormone and over-the-counter vitamin D supplements. 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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