July 22, 2014

OPKO Granted Patent from US Patent & Trademark Office for RAYALDEE

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK), a multinational biopharmaceutical and diagnostics company, today announced that the United States Patent and Trademark Office granted OPKO a patent covering *RAYALDEE*™, the Company's product to treat secondary hyperparathyroidism (SHPT) in patients with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency. The new patent (US Pat. No. 8,778,373) provides OPKO with additional intellectual property protection covering controlled release administration of a vitamin D compound. OPKO is on schedule to announce top-line results from the first pivotal phase 3 trial for *RAYALDEE* in the third quarter of 2014 and file a New Drug Application (NDA) with the FDA in the first quarter of 2015.

About *RAYALDEE*

RAYALDEE is a first-in-class oral vitamin D prohormone treatment being developed for SHPT in stage 3 and 4 CKD patients with vitamin D insufficiency. It has a proprietary modified-release formulation designed to gradually and reliably raise serum total 25-hydroxyvitamin D (prohormone) concentrations to targeted levels (at least 30 ng/mL) while avoiding upregulation of CYP24, a cytochrome P-450 enzyme that reduces the PTH lowering potency of current vitamin D supplements. Activation of calcifediol, the active ingredient in *RAYALDEE*, by the kidney is tightly regulated, preventing excessive elevation of serum calcium and related side effects which encumber current vitamin D hormone therapies and promote vascular and renal calcification. Once approved, *RAYALDEE* is expected to address an approximate 4 million CKD stage 3 and 4 patients in the U.S. and many more, elsewhere, with SHPT and vitamin D insufficiency.

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 http://www.opko.com.

SAFE HARBOR STATEMENT

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), regarding product development efforts and other non-historical facts about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects, including statements regarding our ability to successfully launch and commercialize proprietary renal disease products, expectations about RAYALDEE, its market potential, that it will address the approximately 4 million patients in the US, and many more elsewhere, with stage 3 or 4 CKD, SHPT and vitamin D insufficiency, that RAYALDEE will be a valuable new treatment for CKD patients, the expected timing for completion of our clinical trials for

RAYALDEE, announcement of top line results, and the submission of an NDA, whether the trials for RAYALDEE will continue to proceed on schedule and on budget, and that we will be able to successfully develop, obtain approval for and launch sales of 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 filings with the Securities and Exchange Commission, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, including the risks that the phase 3 clinical trials for RAYALDEE may not be successful or achieve the expected results or effectiveness, and may not generate data that would support the approval or marketing of this product for the indications being studied, 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.

FTI Consulting
Investor Relations
Barbara Ryan, 212-850-5679
Managing Director
Barbara.Ryan@fticonsulting.com
or
Media Relations
Kimberly Ha, 212-850-5612
Senior Director
Kimberly.Ha@fticonsulting.com

Source: OPKO Health, Inc.