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OPKO Partner Vifor Fresenius Receives Marketing Approval for RAYALDEE in Canada

MIAMI, July 16, 2018 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) announced today that the Company's partner Vifor Fresenius Medical Care Renal Pharma (VFMCRP) has received approval from Health Canada to market RAYALDEE® in Canada for the treatment of secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and vitamin D insufficiency.

"We established a global development and commercialization plan for RAYALDEE as this therapy addresses an important medical need in CKD patients worldwide, and we want to ensure that as many people as possible have access to its benefits," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO Health. "We congratulate our partner Vifor Fresenius on their achievement and thank them for the dedication and hard work they put into reaching this milestone event."

RAYALDEE is an extended-release prohormone of calcitriol, the active form of vitamin D_3. The product is the first and only such therapy approved by the U.S. Food and Drug Administration (FDA) that both raises serum 25-hydroxyvitamin D and lowers blood levels of intact parathyroid hormone. RAYALDEE is indicated in the U.S. for the treatment of SHPT in adults with stage 3 or 4 CKD and vitamin D insufficiency. It is not indicated in patients with stage 5 CKD or end stage renal disease on dialysis.

OPKO Health launched RAYALDEE in the U.S. in November 2016.

About OPKO Health, Inc.
OPKO Health is a diversified healthcare company that seeks to establish industry-leading positions in large, rapidly growing markets. Our diagnostics business includes BioReference Laboratories, the nation's third largest clinical laboratory with a core genetic testing business and a 400-person sales and marketing team to drive growth and leverage new products, including the 4Kscore® prostate cancer test and the Claros® 1 in-office immunoassay platform. Our pharmaceutical business features RAYALDEE, OPK88003, a once- or twice-weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, OPK88004, a SARM (Selective Androgen Receptor Modulator) for treating BPH (Benign Prostatic Hypertrophy), OPK88002, an NK-1 antagonist to treat pruritus (itching) in dialysis patients, and OPK88001, a proprietary oligonucleotide to treat Dravet syndrome. In addition, the Company is advancing its CTP technology, which includes a long-acting hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer). OPKO also has production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is available at 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 product development efforts and the expected benefits of our products, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects, including when VFMCRP will commence commercialization of RAYALDEE in Canada and when or if RAYALDEE will be commercially introduced in other geographies. 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 liquidity issues and the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, 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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