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OPKO Health Enters into Exclusive Agreement with Japan Tobacco to Develop and Commercialize RAYALDEE® in Japan

OPKO to receive up to $118 million in upfront and milestone payments, plus tiered double-digit royalties on product sales

MIAMI, Oct. 12, 2017 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ:OPK) announced that its subsidiary EirGen Pharma has entered into an exclusive agreement with Japan Tobacco Inc. (JT) for the development and commercialization in Japan of RAYALDEE® for the treatment of secondary hyperparathyroidism (SHPT) in non-dialysis and dialysis patients with chronic kidney disease (CKD).

Under the terms of the agreement, JT will make an upfront payment to OPKO of $6 million with another $6 million payment to be made upon initiation of OPKO's planned phase 2 study of RAYALDEE in U.S. dialysis patients. In addition, OPKO will be eligible to receive up to an additional $31 million in development and regulatory milestones and $75 million in sales based milestones. JT will also pay OPKO tiered, double digit royalties on net product sales. JT will be responsible for all regulatory approvals and commercial activities pertaining to RAYALDEE in Japan. According to JT, an estimated 13.3 million people in Japan have CKD and more than 300,000 are undergoing dialysis, with both patient populations increasing due to the aging population.

"JT, together with its subsidiary Torii Pharmaceuticals, has a strong and growing franchise in hemodialysis and renal diseases, which makes JT an ideal partner to bring RAYALDEE to physicians and patients in Japan," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "We believe JT and Torii's innovative marketing activities and their established network with Japanese nephrologists will accelerate adoption of RAYALDEE in this key market. We are confident this collaboration will substantially expand access to the important clinical benefits of RAYALDEE for Japanese patients with CKD."

RAYALDEE is an extended-release prohormone of calcitriol, the active form of vitamin D_3 that 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 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, an FDA approved treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency (launched in November 2016), VARUBI® for chemotherapy induced nausea and vomiting (oral formulation launched by partner TESARO and IV formulation pending FDA approval), OPK88003, a once weekly oxyntomodulin for type 2 diabetes and obesity that is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia and other urologic and metabolic conditions. Our biologics business includes hGH-CTP, a once weekly human growth hormone injection (in phase 3 and partnered with Pfizer), and a long acting Factor VIIa drug for hemophilia in phase 2a. We also have production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is available at 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, and products, financial condition, strategies or prospects, including statements regarding expectations about RAYALDEE and the success of the collaboration and licensing agreement with Japan Tobacco, whether Japan Tobacco will successfully develop, obtain regulatory approval for, launch or commercialize RAYALDEE in Japan, 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 Japan, 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 OPKO's 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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