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OPKO Health Enrolls First Patient in Phase 2B Study of OPK88004 to Treat Benign Prostatic Hypertrophy

Enlarged Prostate Affects Approximately 50 Million Men in the U.S.

MIAMI, Nov. 27, 2017 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) ("OPKO" or "the Company"), announces that the Company has enrolled the first patient in a Phase 2b dose ranging trial of OPK88004, its orally administered selective androgen receptor modulator (SARM), to treat men with benign prostatic hypertrophy (BPH) or enlarged prostate. BPH is a non-cancerous condition in which an overgrowth of prostate tissue pushes against the urethra and the bladder, limiting the flow of urine. BPH affects approximately 50 million men in the U.S.

This trial will enroll approximately 125 men with BPH at 30 sites in the U.S. to identify appropriate doses given over a four month treatment period to reduce prostate size, the primary efficacy endpoint of the study. The study will also assess secondary endpoints, including blood prostate specific antigen (PSA) levels and body composition parameters such as lean body mass and fat mass.

Interest in evaluating OPK88004 as a treatment for BPH is based on data from a 12 week study of 350 men who showed significantly **decreased** fat mass, **increased** lean body mass, and **increased** muscle strength without significantly changing PSA levels in the overall population, while reducing PSA levels in men with elevated PSA levels. The selective and antagonistic properties of OPK88004 appear to be well suited to potentially reduce prostate hypertrophy in BPH subjects, while providing anabolic benefits such as increased lean body mass and muscle strength. In previously conducted dog studies, treatment with OPK88004 for 6 months decreased prostate weight by up to 75%, demonstrating the potent antagonistic effects of OPK8004 on androgen receptor activity in the prostate.

"We are enthusiastic to be initiating this study in men suffering from BPH, as there are no adequate treatment options for this common debilitating condition that affects men as they age. We believe that OPK88004 has the potential of establishing a new standard of care for a disease that affects millions of men worldwide," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO Health.

"Given the large number of patients with BPH, we expect to complete the study and to have topline results before the end of 2018," added Dr. Frost.

About Benign Prostatic Hypertrophy
Benign prostatic hypertrophy is a non-cancerous condition in which an overgrowth of prostate tissue pushes against the urethra and the bladder, blocking the flow of urine. Prostate gland enlargement is a common condition in men as they get older.

According to the Mayo Clinic, the severity of symptoms in men with BPH varies, but tend to worsen over time. Common signs and symptoms of BPH include frequent or urgent need to urinate, increased frequency of urination at night (nocturia), difficulty starting urination, weak urine stream or a stream that stops and starts, dribbling at the end of urination, straining while urinating, and an inability to completely empty the bladder.

Medications are the most common treatment for BPH and include alpha blockers and 5-alpha reductase inhibitors, both of which have adverse side effects such as sexual dysfunction, dizziness and retrograde ejaculation. Surgical procedures to treat males with BPH are often associated with complications and lengthy recovery times.

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 and IV forms marketed by partner, TESARO; 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 hypertrophy 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 various production and distribution assets abroad, 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," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding expectations for the market for OPK88004, the expected benefits of OPK88004 and whether it will effectively reduce prostate size and positively impact PSA levels, lean body mass, and fat mass, whether it will provide anabolic benefits while reducing or avoiding prostate hypertrophy, whether the clinical trials for OPK88004 will be successfully completed on a timely basis or at all and whether the data from the trial will support submission or approval, validation and/or reimbursement for OPK88004, the expected timing of commencing and concluding our clinical trials and having top line results, enrollment in clinical trials, and disclosure of results for the trials, the timing of our regulatory submissions, our ability to market and sell any of our products in development, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects. 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 integration challenges for Bio-Reference, EirGen, Transition, and other acquired businesses, 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 OPK88004 and/or any of our compounds or diagnostic products under development may fail, may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of products for the indications being studied or for other indications, 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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