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OPKO Health Announces Landmark Study Showing 4Kscore® Test is Strong Predictor of Prostate Cancer Mortality Published in European Urology

Study of 11,506 men shows that healthy men with an abnormal PSA and a low 4Kscore test result can be safely monitored rather than undergo prostate biopsy

MIAMI, March 16, 2018 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) today announced that data from a landmark study of the 4Kscore® test entitled, **“Twenty-year Risk of Prostate Cancer Death by Midlife Prostate-specific Antigen and a Panel of Four Kallikrein Markers in a Large Population-based Cohort of Healthy Men”** were published online in the peer-reviewed journal, [*European Urology*](#).

Prostate specific antigen (PSA) screening reduces prostate cancer deaths but may lead to harm from over diagnosis and overtreatment of indolent prostate cancer that is not life threatening. The 4Kscore test was designed to specifically detect aggressive prostate cancer and reduce the use of prostate biopsy with its associated risks in men with an abnormal PSA.

The Malmö Diet and Cancer study enrolled 11,506 healthy men between the ages of 45 and 73 from 1991-1996 who had no previous PSA testing and very limited PSA testing following enrollment. When entering the study, a blood sample was cryopreserved and the men were followed through December 2014 when the blood samples were tested and patients who were diagnosed and died from prostate cancer identified. In the study, there were 317 deaths from prostate cancer. The 4Kscore was measured on 1,223 men diagnosed with prostate cancer and 3,028 controls.

The study found that men aged 60-73 with a PSA ≥ 2.0 ng/mL in their banked sample had a 7.7% (1 in 13) chance of dying from prostate cancer up to 15 years after the sample was collected. These same men were tested with the 4Kscore, and if the 4Kscore test result was $\geq 7.5\%$, indicating high risk for aggressive disease, the risk for death from prostate cancer in the next 15 years was increased to a 13% (1 in 8) chance. These men should have received further evaluation, including consideration of a prostate biopsy. Importantly, the study showed that men with a low risk 4Kscore result of $< 7.5\%$ have a 0%, 0.6% (1 in 167), and 1.7% (1 in 59) risk of death from prostate cancer over the next 5, 10, and 15 years, respectively. These men could have safely avoided a prostate biopsy, and with continued monitoring, would have further lowered their long-term risk.

“The Malmö Diet and Cancer study is a rare natural history study of prostate cancer mortality in the near absence of PSA testing that is unlikely to be repeated in the PSA era,” said Peter Scardino, M.D., urologic oncologist and former Chair of Surgery at Memorial Sloan Kettering Cancer Center. “The results of the study clearly show that most men with an elevated PSA

but a low 4Kscore test result can be safely monitored rather than be subjected to a prostate biopsy.”

“We believe this important study further confirms results of previously reported 4Kscore studies in the United States,” said Phillip Frost, M.D., Chairman and CEO of OPKO Health. “In more than 1,300 American men, including those in our recently published study in the Veterans Administration Healthcare System that had a predominantly African American cohort, the 4Kscore has proven to be a powerful test to identify men who have or may develop aggressive prostate cancer. The 4Kscore test has once again shown to be a reliable guide to the decision of when to perform a prostate biopsy and when to avoid unnecessary biopsies.”

About the 4Kscore Test

The 4Kscore is the only blood test that accurately identifies risk for aggressive prostate cancer. The 4Kscore measures the blood plasma levels of four different prostate-derived kallikrein proteins: Total PSA, Free PSA, Intact PSA and hK2. These biomarkers are combined with a patient's clinical information using a proprietary algorithm that calculates the risk (probability) of finding a Gleason Score 7 or higher prostate cancer. The four kallikrein panel of biomarkers utilized in the 4Kscore test is based on over a decade of research conducted by scientists at Memorial Sloan-Kettering Cancer Center. The 4Kscore test adds new information to the patient-physician shared decision making discussion for patients with an abnormal PSA or other clinical features. The 4Kscore test is included in the 2017 National Comprehensive Cancer Network[®] (NCCN) and 2016 European Association of Urology Prostate Cancer Guidelines.

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 Bio-Reference 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 secondary hyperparathyroidism in stage 3 and 4 chronic kidney disease patients with vitamin D insufficiency (launched in November 2016), 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, a 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," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding the clinical utility for the 4Kscore test, its ability to accurately predict aggressive prostate cancer in men, the expected benefits of the 4Kscore test, whether healthy men with an abnormal PSA and a low 4Kscore test result can be safely monitored rather than undergo a prostate biopsy, 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. 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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