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# OPKO Health's 4Kscore® Test Highlighted in Podium Presentation at 112th American Urological Association Annual Meeting

## Prospective study conducted at Veteran Affairs hospitals confirms 4Kscore accurately predicts aggressive prostate cancer

MIAMI, May 18, 2017 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK), announces that data from a prospective study conducted at Veteran Affairs (VA) hospitals confirming the 4Kscore test's ability to accurately predict aggressive prostate cancer were presented in a podium presentation on May 16, 2017 at the 112<sup>th</sup> American Urological Association (AUA) Annual Meeting in Boston.

The study entitled, **"An Independent, Multi-Institutional, Prospective study in the Veterans Affairs Health System confirms the 4Kscore accurately predicts aggressive prostate cancer,"** was presented by Sanoj Punnen, M.D., Assistant Professor of Urologic Oncology at the Miller School of Medicine, Department of Urology at the University of Miami in Miami, Florida. The study is the second U.S. prospective clinical study to establish the clinical validity of the 4Kscore test to predict the presence of aggressive prostate cancer prior to performing a prostate biopsy.

The VA study was conducted at eight VA hospitals across the United States. A total of 366 men were enrolled in the study, and 208 (56%) of the participants were African American. Of all cancers diagnosed among African American men, prostate cancer is the most common (31% of all cancers), and African American men have a twofold greater risk of prostate cancer mortality compared to non-Hispanic whites.<sup>1</sup>

Overall, the 4Kscore demonstrated a high degree of accuracy for predicting the presence of aggressive (Gleason score 7 and higher) prostate cancer with an area under the receiver operator curve (AUC) of 0.81, significantly better than PSA alone or a clinical model based on PSA. Importantly, there was an equally high ability of the 4Kscore to discern aggressive disease in the African American men compared with the non-African American men (AUC = 0.80 v. 0.84,  $p = 0.32$ ). The calibration and decision curve analysis were also consistent with the performance shown in the first U.S. validation study.

"The VA study confirms the 4Kscore's accuracy in predicting a man's risk of having aggressive prostate cancer and showed that it is an equally effective and vital clinical test for African American men, who have the highest rates of prostate cancer mortality," said Phillip Frost, M.D., Chairman and CEO of OPKO Health. "These positive results add to our growing body of clinical evidence that demonstrate 4Kscore's utility to accurately identify the risk of aggressive prostate cancer. Moreover, these data validate the clinical value of the 4Kscore test in a VA setting and show it to be identical to the performance previously shown in community and academic sites across the U.S. and Europe."

## **About Prostate Cancer**

According to the Prostate Cancer Foundation,<sup>2</sup> “every 3.3 minutes a man is diagnosed with prostate cancer, and millions of men and their families are fighting the disease globally. In the United States, prostate cancer affects 1 in 8 men, making it the most common non-skin cancer in America. This means that a non-smoking man is more likely to develop prostate cancer than he is to develop colon, bladder, melanoma, lymphoma, and kidney cancers combined. In 2017 alone, it is estimated that more than 161,000 men will be diagnosed with prostate cancer, and more than 27,000 will die from the disease. A man of African descent is 73% more likely to develop prostate cancer than a Caucasian man, and more than twice as likely to die from the disease.”

## **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 human kallikrein-related peptidase 2 (hK2). These biomarkers are combined with a patient's age, digital rectal exam (DRE) status (nodule / no nodule), and prior negative biopsy status (yes / no) 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 and leading European institutions. The 4Kscore test provides individualized risk for the presence of aggressive prostate cancer and adds new information to the patient-physician shared decision making discussion. The 4Kscore test is included in the 2016 National Comprehensive Cancer Network 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 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 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), and a long acting Factor VIIa drug for hemophilia in phase 2a. OPKO also has production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information available at [www.opko.com](http://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 generally and in the African American population, the expected benefits of our 4Kscore test, whether clinical trial results are indicative of the 4Kscore test's ability to predict aggressive prostate cancer, 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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<sup>1</sup> <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-facts-and-figures-for-african-americans/cancer-facts-and-figures-for-african-americans-2016-2018.pdf>

<sup>2</sup> <https://www.pcf.org/c/about-the-prostate-cancer-foundation/>

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