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# **OPKO Announces Publication of Large, Prospective, Multi-Institutional Clinical Validation of the 4Kscore™ Test for High Grade Prostate Cancer in the United States**

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced the online publication of a multi-institutional, prospective study of the 4Kscore Test in the journal [\*European Urology\*](#). The results of the study demonstrated that the 4Kscore provides a patient with accurate and personalized information about their risk of having Gleason Score  $\geq 7$  prostate cancer, making it a useful tool for selecting men who have significant disease and are most likely to benefit from a prostate biopsy.

"The clinical validation of the 4Kscore Test has confirmed the accuracy of the 4Kscore Test to identify men harboring a high grade prostate cancer in a diverse United States population," said Dr. Dipen Parekh, Professor and Chair, Department of Urology at the University of Miami and principal investigator for the study. "The results confirm that the 4Kscore Test addresses an important need by providing urologists and their patient a calibrated, individual score for a patient's risk of aggressive prostate cancer and thus provides information useful in the shared decision making discussion between Urologists and patients on whether to undergo a prostate biopsy."

"The United States clinical validation confirms prior work published on multiple cohorts of men that were part of the European Research Study on Prostate Cancer Screening (ERSPC) using the same biomarkers used in the 4Kscore Test," said David Okrongly, President of OPKO Diagnostics. "We are continuing to analyze the patient data coming from our U.S. clinical validation study, in particular to look at associations between the 4Kscore and pathology outcomes in both biopsy and radical prostatectomy specimens."

## **About Prostate Cancer**

According to the World Health Organization, prostate cancer is the second most common cancer in men worldwide, with over 1.1 million men diagnosed with prostate cancer in 2012 and over 300,000 men dying from the disease. In countries like the U.S. where screening for prostate cancer with the PSA test began 20 years ago, there has been a sharp decline in prostate cancer mortality and sharp rise in the incidence of prostate cancers detected. However, most of the prostate cancers that are now detected are an indolent, non-life threatening form of the disease. The net result has been over detection and over treatment of indolent prostate cancers and a rise in the complications from prostate cancer treatment such as erectile dysfunction, urinary obstruction and incontinence.

## **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-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 to calculate 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 shared decision making discussion between a Urologist and patient.

## **About OPKO Health**

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise and novel and proprietary technologies. For more information, visit <http://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), 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 expected benefits of the 4Kscore Test, that the 4Kscore will accurately identify risk for aggressive prostate cancer, whether the test will bring exceptional value to European and U.S. healthcare, whether the test will bring great benefit to patients and the healthcare system by helping avoid the cost of unnecessary, sometimes harmful procedures, whether the 4KscoreTest can make a significant contribution to help target the right patients for aggressive treatment and avoid the harms that accompany over detection and over treatment of indolent prostate cancer, expected growth in use of the test in the U.S. and Europe and whether OPKO will launch the test in Latin America, whether the test will accurately predict high-grade cancers, whether OPKO will successfully commercialize the 4Kscore, the market for and expected sales of 4Kscore, whether the test will be an important benefit for Urologists and their patients, 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 filings with the Securities and Exchange Commission, as well as the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments. 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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