

## OPKO 4Kscore® Recommended in National Comprehensive Cancer Network Guidelines for Prostate Cancer Early Detection

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced the decision of the National Comprehensive Cancer Network (NCCN) to include 4Kscore® as a recommended test in the 2015 NCCN Guidelines for Prostate Cancer Early Detection. The panel concluded that the 4Kscore, as a blood test with greater specificity over the PSA test, is indicated for use prior to a first prostate biopsy or after a negative biopsy to assist patients and physicians in further defining the probability of high-grade cancer.

"We are pleased that the NCCN, an organization leading the way in the establishment of evidence-based guidelines for cancer diagnostics, is recommending the use of the 4Kscore test in the 2015 Prostate Cancer Early Detection Guidelines," said David Okrongly, Ph.D., President of OPKO Diagnostics.

The 4Kscore test has been studied on over 22,000 patients with results published in 12 peer-reviewed scientific publications. "Since its launch, I have been offering and using the 4Kscore test with my patients who have an abnormal PSA prior to a first prostate biopsy and before repeating a prostate biopsy after a negative biopsy," said Dr. Dipen Parekh, Professor and Chair, Department of Urology at the University of Miami and principal investigator for the recently published United States multicenter validation study. "The 4Kscore provides me as a clinician with important information about my patient's individual risk for having aggressive prostate cancer and allows me to have an informed discussion with my patient about whether or not to proceed with a prostate biopsy or safely follow the patient."

The 4Kscore test is the only blood test that accurately identifies an individual patient's risk for high-grade, aggressive cancer. In arriving at their recommendations, the NCCN panel stated: "The challenge is to minimize immediate treatment (over-treatment) of indolent cancers by accurately characterizing the biology of the detected cancer. Identification and selective treatment of aggressive cancers should result in significant decreases in morbidity and mortality while limiting adverse effects on quality of life."

"OPKO is committed to the strategy that effective therapy, particularly cancer therapy, can be greatly enhanced by use of diagnostic tests," said Phillip Frost, M.D., OPKO's Chairman and Chief Executive Officer. "Through diagnostics, we can enable physicians to take a more targeted and precise approach in their treatment strategies and thus improve patient outcomes and lower overall healthcare costs."

## **About the 4Kscore Test**

The 4Kscore is the only blood test that accurately identifies an individual patient's risk for

aggressive prostate cancer, the lethal form of prostate cancer. The 4Kscore uses a proprietary algorithm that incorporates the blood levels of four different prostate-derived kallikrein proteins: Total PSA, Free PSA, Intact PSA and Human Kallikrein-2 (hK2), plus the patient's age, Digital Rectal Exam (DRE) status (nodule / no nodule), and prior negative biopsy status (yes / no) to calculate the percentage risk (probability) of finding a Gleason Score 7 or higher grade of 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 and is established as a recommended standard of care in the 2015 NCCN Prostate Cancer Early Detection Guidelines. The 4Kscore Test provides individualized risk for the presence of aggressive prostate cancer and adds new information to the shared decision making discussion between the Urologist and the 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 <a href="http://www.opko.com">http://www.opko.com</a>.

## 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, the power of the 4Kscore to provide valuable information to accurately identify aggressive prostate cancer and guide clinical decision making, whether it will accurately predict high-grade cancers, improve patient outcomes and reduce health care costs, whether OPKO will successfully commercialize the 4Kscore, and the market for and expected sales of 4Kscore, 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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