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OPKO Announces Publication of Study Using Kallikrein Biomarkers of the 4Kscore® Test in a Large Community-Based Referral Cohort

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced the online publication of a study entitled **"A Four-kallikrein Panel Predicts High-grade Cancer on Biopsy: Independent Validation in a Community Cohort"** in the journal [European Urology](#). The study shows that the four kallikrein panel of biomarkers utilized in the OPKO 4Kscore® Test (Total PSA, Free PSA, Intact PSA and hK2) accurately identifies risk for aggressive prostate cancer prior to prostate biopsy in a population of men referred for prostate biopsy based on Total PSA level and a Free PSA to Total PSA ratio.

The study evaluated the accuracy of the four kallikrein biomarkers in the 4Kscore along with age, DRE and an algorithm (4K algorithm) to predict risk of aggressive prostate cancer in a large community-based setting at Skåne University Hospital, Malmö, Sweden. Like the 4Kscore US Validation study, the Malmö study was conducted on men being referred for prostate biopsy, but in this study, the criteria for referral explicitly included high-risk men with an elevated PSA (greater than or equal to 3 ng/mL) and a low percentage of Free PSA to Total PSA (less than or equal to 20%). These inclusion criteria selected for men with a higher risk for having aggressive prostate cancer than the cohort studied in the 4Kscore US Validation Study. Of the 749 men recruited for the trial, a total of 156 men (21%) were found to have aggressive prostate cancer defined as Gleason score greater than or equal to 7. The results demonstrated that the 4K algorithm discriminated men with aggressive prostate cancer from men who did not have aggressive disease with an area under the curve (AUC) of 0.78. The study also reported that even in this high risk patient population, a substantial number of biopsies (25%) could have been avoided. A decision curve analysis also demonstrated a significant net benefit for the use of the 4K algorithm in this cohort compared to performing biopsy on all men, the current standard of care.

"The Malmö study is the 12th peer-reviewed paper that demonstrated the accuracy of the 4K algorithm to accurately discriminate the presence of aggressive prostate cancer, even in a high risk population," said David Okrongly, President of OPKO Diagnostics. "The results confirm that in a community-based clinical setting, the 4Kscore algorithm improves clinical decision-making for higher risk men with both elevated PSA and low Free PSA to Total PSA ratios, and can safely reduce at least 25% of unnecessary prostate biopsies."

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 increase in the number of prostate cancers detected. However, most of the prostate cancers detected are an indolent, non-life threatening form of the disease. The net result has been a decrease in prostate cancer mortality during the PSA era, but at a cost of over detection and over treatment of indolent prostate cancers.

About the 4Kscore Test

The 4Kscore is the only blood test that accurately identifies risk for aggressive prostate cancer. The 4Kscore measures the blood 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, whether the 4Kscore will accurately identify men more likely to develop distant prostate cancer metastases, whether the 4Kscore will improve long-term prediction of distant prostate cancer metastasis, the power of the 4Kscore to provide valuable information to accurately identify aggressive prostate cancer, including in higher risk populations, and guide clinical decision making, whether it will accurately predict high-grade cancers, whether it will reduce unnecessary biopsies by at least 25%, 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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Source: OPKO Health, Inc.