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OPKO Announces Publication of ProtecT Study Using Kallikrein Biomarkers in 4Kscore Test

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced the online publication of a study entitled **“Predicting High-Grade Cancer at Ten-Core Prostate Biopsy Using Four Kallikrein Markers Measured in Blood in the ProtecT Study”** in the [Journal of the National Cancer Institute](#). 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.

The Prostate Testing for Cancer and Treatment (ProtecT) study is a prospective randomized controlled trial conducted in the United Kingdom for the purpose of evaluating the cost effectiveness of conventional treatments in PSA-detected, clinically localized prostate cancer. Of the 82,428 men recruited for the trial, a total of 6129 men with elevated PSA (≥ 3.0 ng/mL) who underwent prostate biopsy and provided an adequate blood sample were tested for the four kallikreins and their 4Kscore result was determined. The study showed that the four kallikrein panel enhanced aggressive prostate cancer detection compared with PSA and age alone. The area under the curve (AUC) for the 4K model was 0.820 (95% CI = 0.802 to 0.838) while the PSA model was 0.738 (95% CI = 0.716 to 0.761) for high-grade cancer.

“The ProtecT study is the latest in a series of peer-reviewed publications demonstrating the superior clinical value that testing with four kallikrein markers adds to risk prediction for aggressive prostate cancer compared to PSA alone,” said Dr. Peter Scardino, Chair, Department of Surgery, Memorial Sloan Kettering Cancer Center. “The high level of discrimination for differentially detecting high-grade disease supports use of the four kallikrein panel as a reflex test prior to having a prostate biopsy for men with an elevated PSA.”

“The 4Kscore biomarker algorithm has now been tested and published on over 20,000 men in 11 peer-reviewed publications covering multiple US and European cohorts,” said David Okrongly, President of OPKO Diagnostics. “The results all demonstrated the high discrimination and favorable decision curve benefit of the 4Kscore algorithm for predicting the results of prostate biopsy pathology, as well as 20 year outcomes for risk of metastatic prostate cancer.”

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 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, 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, whether the 4Kscore test will be used as a reflex test before prostate biopsy in men with elevated PSA, the power of the 4Kscore to predict the 20 year risk for metastatic prostate cancer and provide valuable information to accurately identify aggressive prostate cancer and guide clinical decision making, whether it will accurately predict high-grade cancers, 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. Peter Scardino, M.D., serves as a member of the OPKO Urology Advisory Board.

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Source: OPKO Health, Inc.