

February 20, 2015



OPKO Announces Publication of 20 Year Outcome Study for Lethal Prostate Cancer Using Kallikrein Biomarkers in 4Kscore Test

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced the online publication of a study entitled "Improving the Specificity of Screening for Lethal Prostate Cancer Using Prostate-specific Antigen and a Panel of Kallikrein Markers: A Nested Case-Control Study" 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 identify men more likely to develop distant prostate cancer metastases, and men with a low 4Kscore were shown to have a low risk of developing metastatic prostate cancer in a 20-year follow up period.

The study is part of the Västerbotten Intervention Project (VIP), which was initiated in 1986 in Västerbotten County, Sweden, and is a population-based study involving a health exam at ages 40, 50, and 60 years of age, where blood was drawn and preserved. The VIP study included data on over 40,000 men, representing greater than 57% of the total background population in Västerbotten County. From this cohort, blood samples of men who developed metastatic prostate cancer and age-matched controls of cancer free men were tested for the four kallikreins and their 4Kscore result was determined.

"The VIP study publication is the first time biomarkers have been shown to improve long-term prediction of distant prostate cancer metastasis," said Dr. Peter Scardino, Chair, Department of Surgery, Memorial Sloan Kettering Cancer Center. "The large increase in discrimination for lethal prostate cancer observed with the use of the four kallikrein panel supports its use as a reflex test before prostate biopsy in men with elevated PSA."

"The VIP publication takes the 4Kscore test beyond predicting histological outcome for Gleason Score greater than or equal to 7," said David Okrongly, President of OPKO Diagnostics. "The VIP trial convincingly demonstrates the power of the 4Kscore to predict the 20 year risk for metastatic prostate cancer and adds valuable information to accurately identify men at high risk for aggressive prostate cancer and confidently avoid a biopsy in men with low 4Kscores."

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, provide valuable information to accurately identify aggressive prostate cancer and guide clinical decision making, help men confidently avoid a biopsy, 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.