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Study Demonstrates OPKO's 4Kscore Test Reduces Unnecessary Prostate Biopsies While Improving Risk Prediction for Aggressive Prostate Cancer

4Kscore Test Results Significantly Influenced Physician-Patient Shared Decision-Making in Clinical Practice and Led to a 64.6% Reduction in Prostate Biopsies

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE: OPK) announced today the results of a study for the 4Kscore® Test's clinical utility in reducing the number of prostate biopsies performed, while increasing the probability of detecting aggressive prostate cancer in men with abnormal prostate-specific antigen (PSA) levels and or digital rectal examination (DRE) results. The peer-reviewed study, *"The 4Kscore® Test Reduces Prostate Biopsy Rates in Community and Academic Urology Practices",* written by Badrinath Konety, MD, et al. and published in the January 2016 edition of Reviews in Urology, a MedReviews, LLC. Publication, which included 611 patients seen by 35 academic and community urologists across the United States, indicated that consideration of results from the 4Kscore tests led to 64.6% fewer prostate biopsies being performed among participating patients.

"The 4Kscore test is a useful tool in identifying men with a significant risk of having an aggressive form of prostate cancer, who are most likely to benefit from a prostate biopsy and selective treatment or intensive intervention, while avoiding biopsies in men who are at low risk for developing aggressive disease," commented lead researcher Badrinath Konety, M.D., Dougherty Family Chair in Uro-Oncology and director of the Institute for Prostate and Urologic Cancers at the University of Minnesota. "Our findings suggest that PSA screening, when coupled with the 4Kscore test, can be made more specific, reduce biopsy complications and overtreatment, and be a more cost-effective solution for managing a patient's prostate health."

Dr. Konety and colleagues evaluated the influence of the 4Kscore test on urologist-patient decisions about whether to perform a biopsy in men who had an abnormal PSA and or DRE result. Test results for patients were stratified into low risk (<7.5%), intermediate risk (7.5%-19.9%) and high risk (≥20%) for developing aggressive prostate cancer. Nearly half (49.3%) of the men were categorized as low risk; 25.7% and 25.0% fell into the intermediate-risk and high-risk categories, respectively. Notably, the 4Kscore test results influenced biopsy decisions in 88.7% of the men. In the three risk groups, a biopsy was avoided in 94.0%, 52.9%, and 19.0% of men in the low, intermediate, and high-risk categories, respectively.

A higher 4Kscore test result was significantly associated with a greater likelihood of having a prostate biopsy ($P < 0.001$). Among the 171 men who had a biopsy, 45 of the 104 cases (43.3%) with a high-risk 4Kscore test result (≥20% risk) were found to have aggressive prostate cancer upon prostate biopsy.

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 test 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, and other clinical information 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 included as a 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, Inc.

OPKO Health, Inc. is a diversified healthcare company that seeks to establish industry-leading positions in large, rapidly growing markets. Our diagnostics business includes Bio-Reference Laboratories, the nation's third-largest clinical laboratory with a core genetic testing business and a 420-person sales force to drive growth and leverage new products, including the 4Kscore® prostate cancer test and the Claros®1 in-office immunoassay platform. Our pharmaceutical business features Rayaldee™, a treatment for secondary hyperparathyroidism (SHPT) in stage 3-4 chronic kidney disease (CKD) patients with vitamin D insufficiency (March 29, 2016 PDUFA date) and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner Tesaro, IV formulation in Phase 3). Our biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a long-acting Factor VIIa drug for hemophilia (entering Phase 2a). We also have production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is available at 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, 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 biopsies by 64.6%, reduce overtreatment and provide a cost effective solution for managing prostate health, 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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