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American Urological Association (AUA) Accepts 4Kscore Test Clinical Study for Plenary Presentation at 2014 Annual Meeting

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced that the American Urological Association (AUA) has accepted "The 4KscoreTM Test as a Predictor of High-Grade Prostate Cancer on Biopsy" as a Late-Breaking Abstract for presentation in Plenary I on Sunday May 18, 2014 at the AUA Annual meeting in Orlando, FL.

The data accepted are from a prospective, blinded study conducted at 26 urology clinics across the United States from October 2013 to January 2014. The data confirm the accuracy of the 4KscoreTM algorithm in a United States population of men referred for prostate biopsy. The 4KscoreTM algorithm, which is based on the values of four different kallikrein blood tests (total PSA, free PSA, intact PSA and hK2) plus age, DRE and prior biopsy status, was originally studied in multiple European cohorts involving over 10,000 patients.

"These are challenging times in urology as we are seeing a decline in men screened for prostate cancer with PSA, yet we know that mortality from prostate cancer has steadily declined since the introduction of PSA screening," said Dr. Stephen M. Zappala, MD FACS of Andover Urology. "The 4KscoreTM test offers new information on the probability of having a Gleason Score ≥ 7 cancer prior to undergoing a prostate biopsy. This is important, because we know that besides the potential side effects of biopsy such as bleeding and infection, up to 80% of prostate biopsies will either be negative for prostate cancer or will indicate a low grade disease that may be better monitored than treated. The 4KscoreTM test will offer both the Urologist and patient new information for the shared decision-making discussion about whether or not to have a prostate biopsy."

"Acceptance as a late-breaking abstract highlights both the quality of the clinical data for the 4KscoreTM test and the urgent need to have a solution for more effective biomarker-based tests for managing prostate cancer risk and the disease itself," said David Okrongly, President of OPKO Diagnostics. "We are looking forward to presenting the full US clinical trial data at the AUA meeting in May."

"The results of the US clinical study are now complete and we are pleased to also announce that we are on track for launch of the 4Kscore Test on March 31, 2014," said Phillip Frost, M.D., OPKO's Chairman and Chief Executive Officer.

About the 4KscoreTM Test

The 4KscoreTM is a convenient blood test that measures the serum levels of four different prostate-derived kallikrein proteins: total PSA, free PSA, intact PSA and hK2. Levels of these

biomarkers are combined with a patient's age and digital rectal exam (DRE) status using a proprietary algorithm to calculate the probability of a finding of aggressive prostate cancer. The 4Kscore™ test is based on over a decade of research of the four kallikrein panel of biomarkers conducted by scientists at Memorial Sloan Kettering Cancer Center and leading research centers in Europe on over 10,000 patients. The information provided by the 4Kscore™ test can help facilitate the shared decision-making process between urologist and patient in determining the advisability of a prostate biopsy.

About Prostate Cancer

In 2013, over 238,000 new cases of prostate cancer will be identified and 29,720 men will die from the disease, according to estimates released by the National Cancer Institute, making it the second most deadly cancer in U.S. men. Prostate cancer is usually first detected by elevations in serum PSA. However, PSA level is often high for reasons unrelated to prostate cancer and, since an elevated PSA level often leads to biopsy, 75% of all prostate biopsies performed are either negative or indicate a low likelihood of aggressive cancer.

ABOUT OPKO HEALTH, INC.

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 OPKO's multi-center validation study will support CLIA validation and reimbursement, whether the 4Kscore™ will be an important tool in the fight against prostate cancer and the prevention of unnecessary biopsies, expectations regarding the success of the product, whether it will provide the probability of having a Gleason Score ≥ 7 prostate cancer prior to undergoing a prostate biopsy, whether it will offer new information for better shared decision-making between a Urologist and patient about whether or not to have a prostate biopsy, whether we will be able to present the full clinical data at the AUA meeting, whether OPKO will be able to successfully launch and commercialize the 4Kscore™ and the expected launch date for the 4Kscore™, the market for and expected sales of 4Kscore™, whether the test will address a significant unmet medical need for more effective biomarker-based tests for managing prostate cancer risk and the disease itself, 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.