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OPKO Commences Pivotal Clinical Validation Study for 4Kscore™ as a Predictor of Prostate Cancer Prior to Biopsy

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE: OPK) has commenced a pivotal, multi-center clinical validation study for the Company's proprietary 4Kscore™ test for the prediction of prostate cancer prior to prostate biopsy. The 4Kscore™ test is based on over a decade of research of a 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 OPKO multi-center study is expected to generate data to support the launch of the 4Kscore™ test as a laboratory developed test through the Company's CLIA laboratory in Nashville, TN. The Company has begun enrolling patients at the first of 13 sites across the United States and is planning to enroll more than 1,200 patients referred for a prostate biopsy over the course of the next few months.

"The OPKO Lab 4Kscore™ test is expected to be an important tool in the fight against prostate cancer and the prevention of unnecessary biopsies," said Dr. Peter Scardino, Chair, Department of Surgery, Memorial Sloan Kettering Cancer Center. "We are optimistic that the newly initiated clinical study will prospectively demonstrate for U.S.-based clinicians and payers the value of the 4Kscore™ test as an important guide in managing patients."

According to a paper titled "The Kallikrein Panel for Prostate Cancer Screening: Its Economic Impact", published online October 26, 2013 in the journal *The Prostate*, it is estimated that about \$1 billion in healthcare costs could be saved annually in the U.S. by implementing a four kallikrein panel test and using the results of the test to determine if a prostate biopsy should be performed.

"We believe OPKO's 4Kscore™ test will address a significant unmet medical need for better tests to identify men at risk for aggressive prostate cancer, while at the same time avoiding unnecessary, costly, and potentially harmful treatments," said Phillip Frost, M.D., OPKO's Chairman and Chief Executive Officer.

"Our clinical study with over 15 of the leading and largest urology centers across the United States is the last step before our commercial launch of the 4Kscore™ in the first quarter of 2014. The data we generate in this clinical study will not only be used for the required CLIA validation, but will also provide important data for securing 4Kscore™ reimbursement," stated David Okrongly, Ph.D., President of OPKO Diagnostics.

About the 4Kscore™ Test

The 4Kscore™ 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 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 multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies.

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 study will generate data to 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 enrollment of the study and the completion date for the study, 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 use of the 4Kscore™ could result in savings of \$1 billion in healthcare costs and address a significant unmet medical need for better tests to identify men at risk for aggressive prostate cancer, while at the same time avoiding unnecessary, costly, and potentially harmful treatments, 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.