

March 31, 2014



OPKO Announces Launch of 4Kscore Test for Prostate Cancer

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) announced the availability of the 4Kscore™ Test through its CLIA-accredited OPKO Lab in Nashville, TN. The laboratory-developed test is designed to enhance the prostate biopsy decision making process that, in the United States, leads to approximately 1 million biopsies being performed annually, with 80% of the results indicating no cancer or a low-grade cancer. The 4Kscore™ Test will help to reduce unnecessary prostate biopsies by providing information on the risk (probability) of having high-grade prostate cancer.

The 4Kscore™ Test was developed by OPKO Lab, a division of OPKO Health, and tested in collaboration with 26 Urology centers across the United States from October 2013 to March 2014. Results showed that the 4Kscore Test™ was highly accurate for predicting the presence of high-grade cancer (Gleason score 7 or higher) prior to prostate biopsy. The full data from the blinded, prospective U.S. clinical validation study will be presented at the AUA Annual Meeting in Orlando, FL on May 18th at Plenary Session I.

“We are pleased to offer the 4Kscore Test™ at OPKO Lab to provide Urologists with new information to inform them of the risk of a patient’s having high-grade prostate cancer and help clarify the decision process surrounding prostate biopsy,” said David Okrongly, President of OPKO Diagnostics.

“We believe the 4Kscore Test™ will be an important benefit for Urologists and their patients and may lead to lower overall healthcare costs,” said Phillip Frost, M.D., OPKO’s Chairman and Chief Executive Officer.

About the 4Kscore™ Test

The 4Kscore™ Test 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 biopsy status (yes / no) using a proprietary algorithm to calculate the risk (probability) of finding a Gleason Score 7 or higher prostate cancer. The 4Kscore Test™ was developed by OPKO Lab, a division of OPKO Health, Inc., and will be performed at OPKO Lab’s CLIA-accredited facility in Nashville, Tennessee. The four kallikrein panel of biomarkers utilized in the test is based on over a decade of research conducted by scientists at Memorial Sloan Kettering Cancer Center and leading European institutions. The information provided by the 4Kscore Test™ can add new information to the shared decision making discussion between a Urologist and patient in determining the advisability of a prostate biopsy.

About Prostate Cancer

In 2014, over 233,000 new cases of prostate cancer will be identified and 29,480 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 elevated for reasons unrelated to prostate cancer. Although an elevated PSA level often leads to biopsy, about 80% of all prostate biopsies performed are either negative or indicate a low likelihood of high-grade 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 the 4Kscore™ will be an important tool in the fight against prostate cancer and help reduce unnecessary prostate biopsies by providing information on the risk (probability) of having high-grade prostate cancer, whether it will accurately predict high-grade cancers, whether the full data will be presented at AUA, whether the test will clarify the decision making process surrounding prostate biopsy, whether OPKO successfully launch and commercialize the 4Kscore™, the market for and expected sales of 4Kscore™, whether the test will be an important benefit for Urologists and their patients and will lead to lower overall healthcare costs, 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.