

June 7, 2016



## **OPKO to Discuss Draft Coverage Determinations for 4Kscore® Test at 2016 Jefferies Healthcare Conference**

MIAMI--(BUSINESS WIRE)-- **OPKO Health, Inc.** (NYSE: OPK) today announced that senior management will discuss recent draft local coverage determinations by certain Medicare Administrative Contractors for OPKO's 4Kscore® test at the Jefferies Healthcare Conference in New York City on Thursday, June 9, 2016 at 11:30 AM (EDT). OPKO previously announced that Novitas Solutions issued a positive draft local coverage determination proposing to establish reimbursement coverage for patients with PSA levels > 3 ng/mL who have not yet had a biopsy, or patients with a PSA level of > 3 ng/mL who have had at least one prior negative biopsy and are considered to be at higher risk. The draft coverage determination was subsequently retired by Novitas due to a potential conflict with another Medicare Administrative Contractor. Palmetto GBA had issued a draft non-coverage determination on May 27<sup>th</sup> for the 4Kscore test.

The 4Kscore test, extensively studied in over 22,000 patients with results presented in 12 peer reviewed scientific publications, improves health outcomes by avoiding unnecessary biopsies while accurately identifying men at high risk for a serious prostate cancer. The 4Kscore test has been adopted into NCCN guidelines and impacts physician and patient decisions while reducing healthcare costs. OPKO had not submitted complete dossiers to either Novitas or Palmetto in advance of their draft determinations and is providing both organizations with a complete data package including the background, extensive clinical validation and physician experience in support of the 4Kscore. OPKO believes there is more than enough scientific and clinical data to justify a positive local coverage decision by Medicare Administrative Contractors and intends to work closely with these organizations to demonstrate the value of the 4Kscore test to improve individual patient care as well as the efficiency of healthcare systems.

The Jefferies presentation will be webcast on the OPKO Investor Relations page of the corporate website at [www.opko.com](http://www.opko.com). To access the live webcast please log on to the OPKO site approximately fifteen minutes before the presentation to register and download any necessary audio software. The audio presentation will be available at this link for a limited time after the live presentation.

### **About the 4Kscore Test**

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 National Comprehensive Cancer Network's 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 physician 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 in stage 3-4 chronic kidney disease patients with vitamin D insufficiency 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), a long-acting Factor VIIa drug for hemophilia (in Phase 2a) and a long acting oxyntomodulin for diabetes and obesity (in Phase 1). 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](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, our ability to obtain positive coverage for the 4Kscore from Novitas, as well as other Medicare Administrative Contractors and payers, whether OPKO has enough scientific and clinical data to justify a positive local coverage decision by any Medicare Administrative Contractor, whether the 4Kscore helps avoid unnecessary biopsies while accurately identifying men at high risk for a serious prostate cancer, the ability to improve patient outcomes and reduce biopsies, 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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Investor relations:

OPKO Health, Inc.

Tara Mackay, +1 305-575-4100

or

Media:

Rooney & Associates

Terry Rooney, +1 212-223-0689

[trooney@rooneyco.com](mailto:trooney@rooneyco.com)

Marion Janic, +1 212-223-4017

[mjanic@rooneyco.com](mailto:mjanic@rooneyco.com)

or

Investors:

LHA

Anne Marie Fields, +1 212-838-3777

[afields@lhai.com](mailto:afields@lhai.com)

Bruce Voss, +1 310-691-7100

[bvoss@lhai.com](mailto:bvoss@lhai.com)

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