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OPKO 4Kscore® Recommended in 2016 European Association of Urology Prostate Cancer Guidelines

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced the decision of the European Association of Urology (EAU) Prostate Cancer Guidelines Panel to include the 4Kscore® Test in the 2016 EAU Guidelines for Prostate Cancer. The panel concluded that the 4Kscore, as a blood test with greater specificity over the PSA test, is indicated for use prior to a first prostate biopsy or after a negative biopsy to assist patients and physicians in further defining the probability of high-grade cancer.

"The EAU Prostate Cancer Guidelines Panel is an international, multi-disciplinary group of specialists in prostate cancer diagnosis and treatment," said Dr. Alberto Briganti, Department of Urology, San Raffaele Scientific Institute, Milan, Italy. "The decision to include the 4Kscore in the guidelines indicates that the Panel views the 4Kscore Test as having achieved an appropriate level of clinical evidence to recommend its use for both assessment of asymptomatic men prior to a first prostate biopsy and as an additional investigational test to be done after a negative prostate biopsy."

The 4Kscore test has been studied on over 22,000 patients with results published in 12 peer-reviewed scientific publications. The 4Kscore test is the only blood test that accurately identifies an individual patient's risk for high-grade, aggressive cancer.

About the 4Kscore Test

The 4Kscore, a laboratory developed test, 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 both the 2016 NCCN Early Detection Guidelines and the 2016 EAU Guidelines for prostate cancer. 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

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, reduce overtreatment and provide a cost effective solution for managing prostate health, whether OPKO will successfully commercialize the 4Kscore in the U.S. and Europe, 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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OPKO Health, Inc.

Tara Mackay, 305-575-4100

Investor Relations

or

Media

Rooney & Associates

Terry Rooney, 212-223-0689

trooney@rooneyco.com

or

Marion Janic, 212-223-4017

mjanic@rooneyco.com

or

Investors

LHA

Anne Marie Fields, 212-838-3777

afields@lhai.com

or

Bruce Voss, 310-691-7100

bvoss@lhai.com

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