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# OPKO Health Receives Proposed/Draft Medicare Local Coverage Determination for 4Kscore® Test

MIAMI--(BUSINESS WIRE)-- **OPKO Health, Inc.** (NYSE:OPK) ("OPKO" or the "Company") announces that Novitas Solutions has issued a draft local coverage determination for the 4Kscore® Test, the only blood test that accurately identifies an individual patient's risk for high-grade, aggressive prostate cancer. Novitas Solutions is a Medicare Administrative Contractor (MAC) for Medicare jurisdictions L and H, with responsibility for nearly 10 million Medicare beneficiaries in New Jersey, Pennsylvania, Maryland, the District of Columbia and Texas, among other geographies.

The draft local coverage determination is posted to the Medicare Coverage Database on the Centers for Medicare & Medicaid Services (CMS) website, and proposes 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.

"This first MAC determination is a major milestone for the 4Kscore Test as it expands access to a potentially life-saving tool," said Phillip Frost, M.D., OPKO's Chairman and Chief Executive Officer. "We believe this decision by Novitas will help accelerate further coverage decisions by other payers, and will encourage adoption of the 4Kscore Test by physicians and patients. More importantly, it will allow broader access to this important test, which can assist patients and physicians in further defining a patient's risk of having a high-grade prostate cancer that requires immediate or aggressive treatment."

The draft local coverage determination follows the 4Kscore's inclusion as a standard-of-care in the 2015 National Comprehensive Cancer Network Guidelines and in the 2016 European Association of Urology Prostate Cancer Guidelines for Prostate Cancer.

## 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 (SHPT) in stage 3-4 chronic kidney disease (CKD) patients with vitamin D insufficiency (pending FDA approval) 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](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, the ability to obtain broader access to the tests for patients, our ability to accelerate coverage decisions, 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, 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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OPKO Health, Inc.

Tara Mackay, 305-575-4100  
Investor Relations

or

Media

Rooney & Associates

Terry Rooney, 212-223-0689

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

or

Marion Janic, 212-223-4017

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

or

Investors

LHA

Anne Marie Fields, 212-838-3777

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

or

Bruce Voss, 310-691-7100

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

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