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OPKO Plans to Address Draft Local Coverage Determination Published by Novitas Solutions for 4Kscore Test

MIAMI, May 18, 2018 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (Nasdaq:OPK) today announced that Novitas Solutions, Inc. issued a draft local coverage determination (LCD) for the 4Kscore test®. The draft LCD is a proposed non-coverage policy for the 4Kscore test for Medicare and, prior to its effectiveness, is subject to a public comment period ending July 5, 2018. OPKO plans to submit comments during this time period.

The 4Kscore test has been included in the National Comprehensive Cancer Network Guidelines® (NCCN) since 2015, and European Association of Urology Prostate Cancer Guidelines since 2016. Recommendations are based upon expert panels' assessment of peer reviewed literature to provide clinical standards for prostate cancer care. Both guidelines recommend the 4Kscore test can be used as an aid in decision making before a first or repeat prostate biopsy in men with elevated PSA or other clinical symptoms. 4Kscore test has 95% sensitivity and 93% Negative Predictive Value for the identification of aggressive prostate cancer in patient population recommended by NCCN.

The 4Kscore test has been ordered by more than 9,000 practicing physicians worldwide and extensively studied with results presented in 18 peer-reviewed scientific publications involving more than 25,000 patients. Results of five new studies covering the 4Kscore test will be presented at the American Urological Association's 2018 Annual Meeting this weekend in San Francisco, including the second study demonstrating the 4Kscore test's ability to predict prostate cancer mortality in men with elevated PSA. A study will also be presented at the American Society Clinical Oncology meeting in June 2018 demonstrating the 4Kscore has clinical utility for management decisions of men diagnosed with low and intermediate risk prostate cancer due to its strong association with radical prostatectomy pathology outcome.

"The 4Kscore test has proven to be a significant benefit to my patients, by both identifying those men who are at higher risk of significant prostate cancer who would benefit from a prostate biopsy, while also helping me to avoid biopsies in men who are at low risk," said Edward Schaeffer, MD, PhD, Chair of the Department of Urology at Feinberg School of Medicine and Program Director of the Genitourinary Oncology Program at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University. "There are numerous cases where the PSA may not have led to a biopsy, but an elevated 4Kscore led to finding aggressive prostate cancer early enough to be beneficial. It would be a real loss if 4Kscore was not available to assist in making the best decision for my patients."

Novitas Solutions is an administrative services processing company for government-sponsored health care programs on behalf of the federal government, including the Centers for Medicare and Medicaid Services. Novitas serves as the Medicare Administrative

Contractor for a jurisdiction that includes the State of New Jersey, where OPKO's BioReference Laboratories is located and where all 4Kscore test samples are processed.

About OPKO Health, Inc.

OPKO Health is a diversified healthcare company that seeks to establish industry leading positions in large, rapidly growing markets. Our diagnostics business includes BioReference Laboratories, the nation's third largest clinical laboratory with a core genetic testing business and a 400-person sales and marketing team 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, an FDA-approved treatment for secondary hyperparathyroidism in stage 3 and 4 chronic kidney disease patients with vitamin D insufficiency (launched in November 2016), OPK88003, a once- or twice-weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, OPK88004, a SARM (Selective Androgen Receptor Modulator) for treating BPH (Benign Prostatic Hypertrophy), OPK88002, an NK-1 antagonist to treat pruritus (itching) in dialysis patients, and OPK88001, a proprietary oligonucleotide to treat Dravet syndrome. In addition, the Company is advancing its CTP technology, which includes a long-acting hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer). OPKO also has production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is available at www.opko.com.

Cautionary Statement Regarding Forward-Looking Statements

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 financial performance and expectations regarding the 4Kscore, expected benefits of the 4Kscore test, the Company's ability to obtain a positive coverage determination for the test, whether the test will accurately identify those men who are at higher risk of significant prostate cancer who would benefit from a prostate biopsy while also helping to avoid biopsies in men who are at low risk, product development efforts and the expected benefits of our products, 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 Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and in our other filings with the Securities and Exchange Commission, as well as integration challenges for Bio-Reference, EirGen, Transition, and other acquired businesses, liquidity issues and the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied. 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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