Future Non-Coverage Determination for 4Kscore Test Posted by Novitas

MIAMI (January 31, 2019) – OPKO Health, Inc. (NASDAQ: OPK) today announced that Novitas Solutions, Inc. has issued a notice of a future non-coverage determination for the 4Kscore test® to be effective March 20, 2019. The notice released by Novitas today does not appear to be different from the draft local coverage determination released by Novitas on May 18, 2018. OPKO is evaluating options to appeal the decision and undertake other steps with the U.S. Centers for Medicare & Medicaid Services (CMS) in an effort to have this determination rescinded or reversed.

"The 4Kscore test is proven to offer significant benefits to patients. It can identify men at higher risk of aggressive prostate cancer who will benefit from a prostate biopsy, while also helping to avoid biopsies in men who are at low risk," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO Health. "We remain committed to our goal of widespread and affordable access to 4Kscore. Our test provides an additional important tool in the prostate cancer diagnostic paradigm and helps guide treatment decisions for both physicians and patients. We have also been working with the U.S. Food and Drug Administration and intend to submit the 4Kscore test to the FDA next quarter for approval."

"The 4Kscore test has become an invaluable component to my evaluation of patients with an elevated serum PSA," stated Mitchell Benson, M.D., Herbert and Florence Irving Professor of Urology, Columbia University Irving Medical Center and New York Presbyterian Hospital. "The results of the test dictate the judicious use of prostate MRI and is used to determine the need for prostate biopsy. The 4Kscore test is integral to the care of my patients."

This determination by Novitas was made despite widespread support for the test from leading urologists. The 4Kscore test has been included in the National Comprehensive Cancer Network Guidelines® (NCCN) since 2015 and the European Association of Urology Prostate Cancer Guidelines since 2016. Recommendations for inclusion in these guidelines to provide clinical standards for prostate cancer care are based upon the assessment by expert panels of peer-reviewed literature. Both guidelines recommend that the 4Kscore test be used as an aid in decision making before a first or repeat prostate biopsy in men with elevated PSA or other clinical symptoms. The 4Kscore test has 95% sensitivity and 93% negative predictive value for the identification of aggressive prostate cancer in the patient population recommended by the NCCN. We have and will continue to commit substantial efforts to obtaining broad reimbursement coverage for the 4Kscore test. We have obtained a positive coverage decision from at least one national private payor and pricing agreements from several regional payors.

The 4Kscore test has been ordered by more than 12,000 practicing physicians worldwide, with over 200,000 tests ordered and extensively studied in more than 25,000 patients with results presented in 18 peer-reviewed scientific publications. Results of five new studies covering the 4Kscore test were presented at the American Urological Association's 2018 Annual Meeting, including a study demonstrating the test's ability to stratify risk of prostate cancer mortality in men with elevated PSA.

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. In diagnostics, its BioReference Laboratories is the nation's third largest clinical laboratory; GeneDx is a rapidly growing genetic testing business; the 4Kscore® prostate cancer test is used to confirm an elevated PSA to help decide about next steps such as prostate biopsy; Claros® 1 is a point-of-care diagnostics platform with PSA and testosterone as the most advanced in development. In our pharmaceutical pipeline, RAYALDEE is our first pharmaceutical product to be marketed. OPK88003, a once-weekly oxyntomodulin for type 2 diabetes and obesity in Phase 2 clinical trials, is among a new class of GLP-1 – glucagon receptor dual agonists. OPK88004, a SARM (selective androgen receptor modulator) is currently being studied for benign prostatic hyperplasia but for which we are exploring other potential indications. The Company's most advanced product utilizing its CTP technology, a once-weekly human growth hormone for injection, is in Phase 3 trials, and is partnered with Pfizer. OPKO also has research, development, production and distribution facilities abroad. 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 about expected benefits of the 4Kscore test, whether we will be able to successfully appeal the Novitas decision and undertake other steps with the CMS to have this determination rescinded or reversed, statements about our ability to obtain broad reimbursement coverage for the test, whether we will submit the 4Kscore test to the FDA for clearance or approval next quarter, as well as other non-historical statements about our expectations, beliefs or intentions. 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. 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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