November 15, 2019

Novitas Issues Final Local Coverage Determination for the 4Kscore® Test

Medicare coverage for patients meeting certain criteria to begin as of December 30, 2019

MIAMI, Nov. 15, 2019 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (OPK)** today announced that Novitas Solutions, Inc. has issued its final Local Coverage Determination (LCD) for Medicare payments for the 4Kscore® test with defined coverage criteria, effective December 30, 2019. Full text of the final LCD can be found here.

"The 4Kscore® test is widely recognized by clinicians to be an important tool in the diagnostic paradigm for prostate cancer, and we are pleased with the final LCD by Novitas," said Jon R. Cohen, MD, Executive Chairman of BioReference Laboratories, Inc. "This final determination is expected to significantly improve men's access to the 4Kscore® test. We look forward to continuing to provide urologists with a test that accurately determines a man's risk of aggressive prostate cancer."

The 4Kscore® test is used in men after an abnormal prostate-specific antigen (PSA) or digital rectal exam (DRE) result. It provides the risk of finding high-grade prostate cancer if biopsy were to be performed and has the potential to minimize avoidable biopsy procedures. Data from two prospective clinical studies involving approximately 1,500 patients in urology centers in the U.S. demonstrated that the 4Kscore® test had 94% sensitivity and 95% Negative Predictive Value for detecting aggressive prostate cancer. The 4Kscore® test has been used by more than 4,000 urologists, with more than 250,000 tests performed. The test has been included in the National Comprehensive Cancer Network Guidelines® (NCCN) since 2015, and European Association of Urology Prostate Cancer Guidelines since 2016. OPKO has offered the 4Kscore® test since 2014 in the U.S., Europe and elsewhere.

The test is currently available at BioReference Laboratories, an OPKO Health Company, through its specialty oncology and urology division, GenPath. For more information about the 4Kscore® test, please visit https://4kscore.com/.

Novitas serves as the Medicare Administrative Contractor for a jurisdiction that includes New Jersey, where OPKO's BioReference Laboratories, Inc. is located and where all 4Kscore® testing is performed.

About the 4Kscore Test
The 4Kscore test measures blood levels of four prostate specific biomarkers and combines these results with other clinical information, including age, digital rectal examination (DRE) and prior biopsy history in a proprietary algorithm to provide a percent risk for a high-grade Gleason score greater than or equal to 7 cancer on biopsy. The 4Kscore can be used prior to biopsy, or after a negative biopsy, and can predict the likelihood of cancer spreading to other parts of the body in the next 20 years. For more information on the 4Kscore test,

please visit www.4kscore.com.

About BioReference Laboratories, Inc.
BioReference provides comprehensive testing to physicians, clinics, hospitals, employers, government units, correctional institutions and medical groups. The company is in network with the five largest health plans in the United States, operates a network of 10 laboratory locations, and is backed by a medical staff of more than 160 MD, PhD and other professional level clinicians and scientists. With a leading position in the areas of genetics, women's health, maternal fetal medicine, oncology and urology, BioReference and its specialty laboratories, GenPath and GeneDx, are advancing the course of modern medicine. For more information, visit https://www.bioreference.com.

About OPKO Health, Inc.
OPKO Health is a diversified healthcare company. In diagnostics, its BioReference Laboratories is one of the nation's largest full-service clinical laboratories; GeneDx is a rapidly growing genetic testing business; the 4Kscore® prostate cancer test is used to assess a patient's individual risk for aggressive prostate cancer following an elevated PSA and to help decide about next steps such as prostate biopsy; Claros® 1 is a point-of-care diagnostics platform with a total PSA test approved by the FDA. In our pharmaceutical pipeline, RAYALDEE is our first pharmaceutical product to be marketed. OPK88003, a once-weekly oxyntomodulin for type 2 diabetes and obesity reported positive data from a Phase 2 clinical trial. It's among a new class of GLP-1/glucagon receptor dual agonists. OPK88004, a SARM (selective androgen receptor modulator) is currently being studied for various potential indications. The company's most advanced product utilizing its CTP technology, a once-weekly human growth hormone for injection, successfully met its primary endpoint and key secondary endpoints in a Phase 3 study 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 regarding the 4Kscore test and its benefits, whether the LCD will improve men's access to the 4Kscore test, whether the test will accurately determine a man's risk of aggressive prostate cancer and minimize avoidable biopsies, 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 the OPKO Health, Inc. Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and in its other filings with the Securities and Exchange Commission. 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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