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OPKO Health Receives FDA Approval for the Point-of-Care Sangia PSA Test with the Claros® 1 Analyzer

MIAMI, Feb. 01, 2019 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** today announced that the U.S. Food and Drug Administration (FDA) has approved the Company's point-of-care Sangia Total Prostate Specific Antigen (PSA) Test using the Claros 1 Analyzer. The product is indicated to quantitatively measure total PSA in whole blood from a fingerstick of blood collected by a healthcare professional and is used in conjunction with a digital rectal exam as an aid in the detection of prostate cancer in men aged 50 years and older.

There are 25 million PSA tests performed in the United States annually. The Company plans to expand the number of assays on the Claros 1 technology platform through future submissions to the FDA, including a planned submission for a testosterone test later this year.

"We are pleased that the FDA has approved our point-of care Sangia PSA Test with the Claros 1 Analyzer. This approval contributes to our growing urology franchise and affords us the momentum to expand the test menu on the Claros 1 technology platform in the future," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO Health. "We believe that a PSA test that provides results in the physician's office will significantly benefit the diagnostic paradigm for prostate cancer," added Dr. Frost.

The Claros 1 Analyzer is a novel diagnostic instrument system that can provide rapid, quantitative test results in 10 minutes – right in the physician's office. The Claros 1 incorporates cutting edge microfluidic technology in a credit card sized disposable test cassette. No external reagents or blood sample preparations are required. The microfluidic assay cassette is inserted into a desktop size Claros 1 Analyzer. Data supporting the approval of Sangia PSA test include field use studies at multiple clinics to demonstrate accuracy and sensitivity comparable to that obtained with FDA approved large analyzers used by central reference laboratories using large blood samples drawn from veins.

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 (FDA approved) 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 expectations for the Sangia Total PSA Test using the Claros 1 Analyzer, our ability to expand the number of assays for the Claros system and make additional submissions to the FDA, including for testosterone, whether PSA testing in a physician's office will significantly benefit the diagnostic paradigm for prostate cancer, 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, our ability to commercialize the Sangia PSA Test, 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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