January 9, 2017

OPKO Announces Initiation of Claros® 1 Clinical Trial for Total PSA

MIAMI, Jan. 09, 2017 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) today announced the initiation of a multi-center clinical validation study for the Company's proprietary Total PSA microfluidic assay cassette running on the Claros® 1 in-office immunoassay analyzer. Over the next several months, the Total PSA clinical study will enroll approximately 1,000 patients at 15 sites across the United States. The clinical study data is expected to support the Premarket Approval (PMA) application to the FDA for the Total PSA assay and the Claros 1 analyzer, as well as pave the way for future FDA submissions of additional assays to be performed on the Claros 1 instrument.

"The Claros 1 analyzer delivers highly sensitive, quantitative immunodiagnostic test results with unprecedented convenience for the patient and the medical professional," said David Okrongly, Ph.D., President of OPKO Diagnostics. "The Total PSA assay is the first of a series of immunodiagnostics tests that we believe will make the Claros 1 platform a significant component of 21st century precision medicine."

At the heart of the Claros 1 platform is the patented microfluidics and gold nanoparticle signal amplification technology that combine to deliver accurate, high sensitivity results – from a fingerstick drop of blood – in approximately 10 minutes.

"We believe that access to rapid immunodiagnostic test results in the physician's office will be game changing for physicians in allowing them to provide enhanced quality of care for their patients," said Phillip Frost, M.D., OPKO's Chairman and Chief Executive Officer.

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 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, an FDA-approved treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency (launched in November 2016), VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO and IV formulation PDUFA date: January 2017), TT401, 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, and TT701, an androgen receptor modulator for androgen deficiency indications. Our biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in phase 3 and partnered with Pfizer), a long-acting Factor VIIa drug for hemophilia (in phase 2a) and a long-acting oxyntomodulin for diabetes and obesity (in phase 1). 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.

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 Company's Claros® 1 in-office immunoassay analyzer, whether the clinical study for the Total PSA test will be successful and support a PMA and pave the way for future FDA submissions of additional assays, whether we will be able to successfully commercialize the test for Total PSA and other immunodiagnostics tests, whether it will be game changing for physicians and enhance the quality of care of patients, that the Claros 1 system will provide highly sensitive, quantitative immunodiagnostic test results with unprecedented convenience, the market for and expected sales of the test, 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.

Contacts:

OPKO Health, Inc.

Tara Mackay, 305-575-4100

Investor Relations

or

Media

Rooney & Associates

Terry Rooney, 212-223-0689

trooney@rooneyco.com

or

Marion Janic, 212-223-4017

mjanic@rooneyco.com

or

Investors

LHA

Anne Marie Fields, 212-838-3777

afields@lhai.com

or

Bruce Voss, 310-691-7100

bvoss@lhai.com

Source: OPKO Health Inc.