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OPKO Health Submits Premarket Approval Application with FDA for a Point-of-Care PSA Test with the Claros® 1 Platform

Addresses a $625 million U.S. market opportunity

MIAMI, Nov. 07, 2017 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ:OPK) ("OPKO" or "the Company") announces the filing of a Premarket Approval (PMA) application with the U.S. Food and Drug Administration (FDA) for the Total PSA test with the Claros® 1 immunoassay analyzer. The filing contains clinical data from the Company's 864-patient Total PSA clinical study.

The Claros 1 immunoassay analyzer is a novel diagnostic instrument system that can provide rapid, quantitative blood test results in 10 minutes - right in the physician's office. The Claros 1 incorporates cutting edge microfluidics in a credit card sized disposable test cassette. No external reagents, no instrument calibration and almost no maintenance are required. The microfluidic cassette is inserted into a desktop analyzer and produces highly accurate results during the same office visit. A similar test result coming from a clinical laboratory can take up to a week.

OPKO Health has concluded a multicenter clinical trial for the first Claros 1 test, the total prostate specific antigen (PSA) test. Data from the clinical study showed that the Claros 1 Total PSA test improved the sensitivity of a digital rectal exam (DRE) to 91%, detecting 2.9 times the prostate cancers compared to DRE alone.

"The PMA filing for the Total PSA with the Claros 1 analyzer marks a significant milestone for OPKO and should pave the way for future FDA submissions of additional assays to be performed using the Claros 1 platform," said Phillip Frost, M.D., OPKO's Chairman and Chief Executive Officer. "The Claros 1 instrument provides access to a series of in-office rapid immunodiagnostic test results, enabling physicians to determine the appropriate course of treatment for a patient during an office visit and enhancing the quality of care and patient experience.

"With more than 25 million PSA tests performed in the U.S. annually, the Claros 1 Total PSA test represents a $625 million market opportunity. Once approved, we plan to leverage BioReference Laboratory's sizeable distribution and marketing capabilities to make this rapid, in-office test available for the benefit of physicians and patients," added Dr. Frost.

OPKO expects to initiate clinical validation studies and to file a 510(k) application for a Claros 1 testosterone test in 2018. OPKO is also working to add additional tests for vitamin D, infectious diseases, cardiology, women's health and companion diagnostics to the Claros 1 menu.

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 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 recently approved by the FDA), OPK88003, a once-weekly oxyntomodulin for type 2 diabetes and obesity that is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia and other urologic and metabolic conditions. Our biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a long-acting Factor VIIa drug for hemophilia in Phase 2a. 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), regarding product development efforts and other non-historical facts about our expectations, beliefs or intentions regarding our business, and products, financial condition, strategies or prospects, including statements regarding expectations about the Total PSA test with the Claros® 1 immunoassay analyzer, whether the test will produce highly accurate results in ten minutes during an office visit, whether the product will be approved by the FDA and whether

the Company can successfully launch and commercialize the product, the expected market for the Total PSA test, and the Company's ability to develop and obtain approval for additional assays using the technology, whether we will initiate clinical validation studies and file a 510(k) for a Claros 1® testosterone test in 2018, and whether we will add additional tests for vitamin D, infectious diseases, cardiology and women's health and companion diagnostics. 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 OPKO's filings with the Securities and Exchange Commission, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable products and treatments, including the risks that others may develop products which are superior to the Claros 1 product, and that the Claros 1 products may not have advantages or prove to be superior over presently marketed products. 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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