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# OPKO Health Announces Commencement of U.S. Clinical Trial for Point-of-Care Prostate Specific Antigen Test

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE: OPK) today announced the commencement of a multi-center clinical study of OPKO's point-of-care diagnostic test for prostate specific antigen (PSA) utilizing its proprietary diagnostic platform. OPKO intends to submit its application to the U.S. Food and Drug Administration for approval of the assay in 2012.

The PSA test on OPKO's platform requires only a finger stick drop of blood and utilizes a novel microfluidics system consisting of a credit card size disposable test cassette and a small but sophisticated desktop analyzer to provide physicians and patients with accurate, lab quality results within minutes. OPKO has already obtained a CE mark for this PSA test in Europe and other markets outside the United States.

The clinical trial is designed for both 510(k) clearance and potential CLIA-waiver of the test. Up to 5 study sites across the United States are participating and we expect to enroll a total of approximately 400 patients. The study will test PSA levels over a 6-month period and is intended to demonstrate equivalence with results obtained with larger laboratory instrumentation. Equivalence necessary to obtain the CE mark has already been confirmed.

"I am pleased to announce the launch of this trial as we continue with our plans to build out a larger panel of urologic tests," said Phillip Frost, M.D., Chairman and CEO of OPKO Health, Inc.

**About OPKO Health, Inc.**

OPKO is a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging its discovery, development and commercialization expertise and novel and proprietary technologies.

*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 OPKO platform and its expected benefits, the platform's ability to provide lab quality results in minutes, the design of the clinical trial, expectations regarding enrollment and the outcome of the trial, including the demonstration of equivalence compared to results obtained with large laboratory instrumentation, the timing of the submission to the FDA for regulatory approval, and our ability to build a larger panel of urologic tests, 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 integration issues involving Claros, 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.*

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Source: OPKO Health, Inc.