OPKO Health Submits De Novo Request to the U.S. FDA for the 4Kscore® Test

MIAMI (June 20, 2019) – OPKO Health, Inc. (NASDAQ: OPK) announces that the Company has submitted a de novo request to the U.S. Food and Drug Administration (FDA) seeking regulatory clearance for the 4Kscore® test. The 4Kscore® test is a blood test used by health care professionals to assess a patient's risk of having aggressive prostate cancer after an abnormal prostate specific antigen (PSA) test result, and before a decision is made to perform a biopsy.

The de novo pathway for approval is available to medical devices of low-to-moderate risk that do not have an approved predicate device. Per FDA guidelines, the Company expects to receive a response to this request within approximately 180 days.

"We are happy to report the submission of our regulatory filing to the FDA for the 4Kscore® test. In multiple prospective controlled clinical studies, the 4Kscore® test has shown consistent high sensitivity and high predictive values to identify men at higher risk of aggressive prostate cancer and who will benefit from a prostate biopsy, while helping to avoid biopsies in men who are at low risk," said Phillip Frost, M.D., OPKO's Chairman and Chief Executive Officer. "We believe FDA clearance for the 4Kscore® test will help to maximize its market availability and reimbursement."

The four biomarkers included in the 4Kscore® test are the result of more than a decade of research by scientists in Europe and the U.S., including scientists from the University of Turku and Memorial Sloan Kettering Cancer Center. Through extensive research and multiple prospective controlled clinical validation studies, including large long-term outcome studies, the 4Kscore® test with its algorithm in place for the last several years, has been shown to stratify subjects into low- and high-risk groups for future prostate cancer metastasis and mortality. The 4Kscore® test has been included in the National Comprehensive Cancer Network Guidelines® (NCCN) and American Urological Association guidelines since 2015, and the European Association of Urology Prostate Cancer Guidelines since 2016.

OPKO has offered the 4Kscore® test since 2014 in the U.S. and Europe.

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 a total PSA test approved by the FDA and testosterone as the most advanced test 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, recently reported positive data from a Phase 2 clinical trial. OPK88003 is 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, 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 regarding expected performance of the 4Kscore® test, whether the test will be cleared by the FDA, the expected timing for the FDA to respond, and whether clearance will expand market availability or reimbursement for 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 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, as well as integration challenges for Bio-Reference, and other acquired businesses, liquidity issues and the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that the 4Kscore and/or any of our compounds or diagnostic products under development may fail, may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of products for the indications being studied or for other indications, that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied. 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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