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OPKO Subsidiary GenPath Women's Health Announces the Availability of ClariTest™

Non-invasive prenatal test that harnesses the power of massively parallel sequencing to screen for fetal chromosomal abnormalities

MIAMI, March 07, 2017 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ:OPK) announces that GenPath Women's Health, a business unit of OPKO Health subsidiary BioReference Laboratories, will offer ClariTest™, a non-invasive prenatal test (NIPT) initially to be performed at Illumina, Inc. (NASDAQ:ILMN) on the Verifi™ platform. This platform utilizes massively parallel sequencing technology to screen for trisomies 13, 18, 21 and sex chromosome abnormalities, with the option to screen for 5 microdeletions including 22q11.2 (DiGeorge syndrome). ClariTest™ can be performed as early as 10 weeks of gestational age, can be performed in twin and egg donor pregnancies, has excellent sensitivity and specificity, and has the lowest failure rate in the industry.

Illumina's most recent clinical evidence study of Verifi™ was comprised of more than 85,000 clinical samples and demonstrated observed sensitivity and specificity of trisomy 21 at greater than 99%. Trisomy 18 and trisomy 13 had observed sensitivity at greater than 97% and specificity at greater than 99%. With the industry's lowest failure rate at 0.1%, Illumina's Verifi™ service can reduce maternal anxiety by requiring fewer redraws and reliably providing fetal genetic information to a greater number of patients and providers.

GenPath Women's Health will ultimately develop and validate its own laboratory-developed test for NIPT using Illumina's sequencing technology. Adoption of Illumina's Verifi™ test allows GenPath to continue to serve the NIPT market using the immense power of whole genome sequencing while developing its own NIPT offering.

"We believe the best way to improve patient care is to unlock the power of whole genome sequencing. We are pleased to partner with BioReference and GenPath Women's Health to expand the use of Illumina technology for women's health. The partnership further extends Illumina's strategy to enable a broader number of customers to offer NIPT on our sequencing technology," said Jeff Hawkins, Vice President and General Manager of Reproductive Genetic Health at Illumina.

"NIPT testing has become an incredibly valuable addition to prenatal care and we are pleased to offer what we believe to be the most technically advanced NIPT test available on the market. ClariTest is a safe option to help pregnant women and their physicians screen patients who are at an increased risk of a fetal chromosome abnormality," said Gregory S. Henderson, M.D., Ph.D., President of BioReference Laboratories. "Patient care is foremost at BioReference and ClariTest provides highly accurate results at an early gestational age. ClariTest is based on the latest advances in technology, offering superior detection rates

compared to conventional screening methods for fetal chromosome abnormalities and can significantly reduce the need for invasive testing, which is associated with an increased risk for adverse pregnancy outcomes, including pregnancy loss."

ClariTest is available from GenPath Women's Health. As a convenience to patients and physicians alike, the laboratory provides easy-to-read results reports available within 5-7 days after testing, access to an industry-leading team of genetic counselors, contracts with most national insurance carriers, direct-to-patient pricing as part of the Community Health Advocacy Program, the ability to interface with most EMR/EHRs, a comprehensive network of patient service centers and other ancillary support services.

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 pending FDA approval), 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 (phase 2), and TT701, an androgen receptor modulator for androgen deficiency indications (phase 2). 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.

About GenPath Women's Health:
GenPath Women's Health and its parent company BioReference Laboratories Inc. are members of the OPKO Health, Inc. (NASDAQ:OPK) group of companies. GenPath Women's Health is a full-service laboratory offering a complete menu of tests for the OB-GYN and women's health providers. Since its inception in 2005, GenPath Women's Health has risen to become one of the premier specialty labs in the country, including the development of an innovative technology platform for sexually transmitted and other vaginal infections, pan-ethnic carrier testing and maternal risk assessment and prenatal diagnosis. GenPath has grown and evolved to become the One Lab for every phase of a patient's life, offering solutions to all women's health testing and service needs. In 2015, GenPath launched an industry-leading line of hereditary cancer testing. More information is available at http://www.genpathdiagnostics.com/womens-health/.

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 ClariTest and the performance of the test, whether it will reliably provide fetal genetic information, whether it offers superior detection

rates and will significantly reduce the need for invasive testing, 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.

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