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OPKO Health's BioReference Laboratories to Participate in the National Cancer Institute NCI-MATCH (Molecular Analysis for Therapy Choice) Phase II Clinical Trial

MIAMI, Aug. 28, 2018 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** today announced that BioReference Laboratories, Inc. (BRL), an OPKO Health company and the third largest clinical laboratory in the United States, has signed a collaboration agreement with the National Cancer Institute (NCI) and ECOG-ACRIN Cancer Research Group (ECOG-ACRIN). This agreement provides for BRL, through its GenPath Oncology Diagnostics division, to participate in the NCI/ECOG-ACRIN precision medicine clinical trial [NCI-MATCH study EAY131 \(NCI-MATCH\)](#).

The purpose of the NCI-MATCH trial is to determine the efficacy of certain cancer therapeutics that target a patient's genetic alterations, regardless of the cancer type. The NCI-MATCH seeks to enroll eligible patients with advanced solid tumors, lymphomas, or myeloma who have progressed on standard treatment for their cancer or have a rare cancer for which there is no standard treatment.

This collaboration is designed for GenPath to notify the treating oncologist at one of the 1,100 participating sites when a genomic alteration is detected by [OnkoSight](#) that is matched to a treatment arm. The treating oncologist will evaluate other eligibility criteria and discuss with the patient the NCI-MATCH trial as a possible treatment option.

"NCI-MATCH participation will allow BioReference Laboratories to offer access to a broader range of clinical trial options for our participating clients' cancer patients," said Dr. James Weisberger, MD, Executive Vice President and Chief Medical Officer at BioReference Laboratories. "This will help increase patient access to targeted precision-based therapies and hopefully improve clinical outcomes."

GenPath's [OnkoSight](#) is a proprietary product line of next generation sequencing assays for hematologic malignancies and solid tumors focused on actionable mutations in common cancers. OnkoSight interrogates clinically actionable oncogenes with high sensitivity and minimal DNA input; as little as ~1 ng of DNA (FFPE). The fast turnaround time of OnkoSight (average of 6 days) provides the oncologist with timely information to manage patient care.

"We are pleased to be a part of the NCI-MATCH trial. BioReference is a national reference laboratory for cancer NGS testing, with current volumes approaching 20,000 cases per year. Participation in the trial will now expand the range of testing options potentially available to the cancer patient populations we serve, and enhance access to genomically matched, targeted therapies," added Dr. Bevan Tandon, MD, Director of Cancer Cytogenomics at BioReference Laboratories.

About BioReference Laboratories, Inc.

BioReference Laboratories is the nation's third largest clinical laboratory, and GeneDx, its subsidiary, is a global leader in genomics testing with a rapidly growing business and an acknowledged expertise in rare and ultra-rare genetic disorders. Together they provide testing services to physicians, clinics, and hospitals, while also advancing drug discovery and development with disease foundations, academic and pharmaceutical partners. For more information, visit www.bioreference.com.

About the NCI-MATCH/EAY131 Trial

The NCI-MATCH study EAY131 trial is a Phase II precision medicine trial that seeks to determine whether matching certain drugs or drug combinations in adults whose tumors have specific gene abnormalities will effectively treat their cancer, regardless of their cancer type. NCI-MATCH was co-developed by the ECOG-ACRIN Cancer Research Group and the National Cancer Institute. It is being led by ECOG-ACRIN.

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 PSA and testosterone as the most advanced 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 in Phase 2 clinical trials, is among a new class of GLP-1 – glucagon receptor dual agonists. OPK88004, a SARM (Selective Androgen Receptor Modulator) for treating BPH (Benign Prostatic Hypertrophy), urinary incontinence, and other conditions, is in clinical trials. 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 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 benefits of our products and services, our ability to offer access to a broader range of clinical trial options for our participating clients' cancer patients, increase patient access to targeted precision based therapies and improve clinical outcomes, and whether we will expand the range of testing options potentially available to the cancer patient populations we serve, the outcome of the NCI-MATCH trial, 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 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 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 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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