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OPKO Health Completes Enrollment in Phase 2b Study of OPK88003 to Treat Type 2 Diabetes and Obesity

MIAMI, June 11, 2018 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) today announced it has completed enrollment of 110 subjects in a Phase 2b dose escalation trial of OPK88003 to treat type 2 diabetes and obesity. OPK88003 is a once weekly injectable oxyntomodulin medicine with GLP-1 and glucagon dual agonist activity. The primary efficacy endpoint is the reduction of HbA1c levels over a 30-week period; weight loss and improvement of blood lipid profiles are secondary endpoints.

Based on preclinical and Phase 2 data, the use of the dual agonist, OPK88003, once-weekly with an optimized dosing regimen, could more effectively improve glucose control, increase weight loss and improve the lipid profile in type 2 diabetics compared with the currently available GLP-1 medicines.

"We are pleased to announce complete enrollment in the Phase 2b dose escalation trial of OPK88003 two months after we initiated the study. Our confidence in this compound is supported by the earlier Phase 2 data, and it is our hope that the outcome of the current study along with our existing body of data will prepare us for a pivotal Phase 3 program," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO Health. "We believe the dual agonist activity of OPK88003 may better control glucose and improve long term cardiovascular outcomes in the growing population of type 2 diabetics worldwide."

According to the American Diabetes Association (ADA), approximately 30 million people in the U.S. have type 2 diabetes and 1.5 million Americans are diagnosed each year. The ADA estimates the annual cost of care for diabetic patients to be \$327 billion, including direct medical costs and reduced productivity¹.

¹ <http://www.diabetes.org/diabetes-basics/statistics/?loc=superfooter>

About OPK88003

OPK88003 was previously evaluated in a blinded Phase 2 clinical trial of 420 patients with type 2 diabetes for 12 weeks, followed by an open-label extension for an additional 12 weeks. The study showed that OPK88003 reduced HbA1c levels by approximately 1.4% and resulted in statistically superior weight loss compared with the comparator, a weekly exenatide. Further, OPK88003 treatment resulted in a favorable decrease in triglycerides and cholesterol versus the weekly exenatide.

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 secondary hyperparathyroidism in stage 3 and 4 chronic kidney disease patients with vitamin D insufficiency (launched in November 2016), OPK88003, 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, OPK88004, a SARM (Selective Androgen Receptor Modulator) for treating BPH (Benign Prostatic Hypertrophy), OPK88002, an NK-1 antagonist to treat pruritus (itching) in dialysis patients, and OPK88001, a proprietary oligonucleotide to treat Dravet syndrome. In addition, the Company is advancing its CTP technology, which includes a long-acting hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer). OPKO also has production and distribution assets worldwide, multiple strategic investments and an active business development strategy. 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," "could," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including product development efforts and the expected benefits of our products, as well as other non-historical statements about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects, expected benefits of OPK88003 to treat type 2 diabetes and obesity, whether it will more effectively improve glucose control, increase weight loss and improve the lipid profile in type 2 diabetics compared with the current GLP-1 therapies on the market, whether the phase 2b data will support commencement of a phase 3 pivotal program, whether the product will better control glucose and improve long-term cardiovascular outcomes and offer various benefits compared with the current once-weekly GLP-1 therapies. 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 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 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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