March 23, 2018

OPKO Health Enrolls First Patient in Phase 2b Study of OPK88003 to Treat Type 2 Diabetes

MIAMI, March 23, 2018 (GLOBE NEWSWIRE) -- **OPKO Health, Inc.** (NASDAQ:OPK) has enrolled the first patient in a Phase 2b dose escalation trial of OPK88003, a once-weekly oxyntomodulin therapy containing dual agonist activity towards GLP-1 and Glucagon receptors, to treat type 2 diabetes and obesity. Based on preclinical and Phase 2 data, the use of once-weekly dual agonists, such as OPK88003, could more effectively improve glucose control, increase weight loss and improve the lipid profile in type 2 diabetics compared to the current GLP—1 therapies on the market.

According to the American Diabetes Association (ADA), the prevalence of type 2 diabetes continues to grow in the U.S., affecting approximately 30 million people, with 1.5 million Americans diagnosed each year. The ADA estimates the annual cost of diabetes in the U.S. to be in excess of $245 billion.[1]

The Phase 2b trial will enroll approximately 110 subjects with type 2 diabetes at up to 35 clinical sites in the U.S. to evaluate a dose escalation regimen of OPK88003 to reduce HbA1c levels over a 30 week treatment period, the primary efficacy endpoint of the study. The study will also assess weight loss and lipid composition, the secondary endpoints.

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 to the comparator, a weekly exenatide. Further, OPK88003 treatment resulted in a favorable decrease in triglycerides and cholesterol in comparison to the weekly exenatide.

"Our confidence in this program is supported by the earlier Phase 2 data and we are enthusiastic to be initiating this study in type 2 diabetics to evaluate the effects of a refined dosing regimen of oxyntomodulin on glucose control and weight loss in preparation for a pivotal Phase 3 program. The dual agonist activity of OPK88003 may provide improved benefits in the treatment of diabetes, resulting in better glucose control and improved long-term cardiovascular outcomes, and we believe it has the potential to offer improved benefits compared with the current once-weekly GLP-1 therapies in a growing diabetes market," stated Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO Health.

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 Bio-Reference 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, a 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," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding OPK88003 and its expected benefits, its effectiveness in treating type 2 diabetes, whether the phase 2 study will be successfully completed, whether OPK88003 will provide similar glucose control and other benefits in improved weight loss and lipid profile to the GLP-1 therapies on the market, whether it will have a favorable effect on cardiovascular outcomes, 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, EirGen, Transition, and other acquired businesses, 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 OPK88003 and 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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[1] http://www.diabetes.org/diabetes-basics/statistics/?loc=superfooter

Source: OPKO Health, Inc.