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OPKO Health Completes Enrollment in Phase 2 Trial Evaluating RAYALDEE as a Treatment for Symptomatic COVID-19 Outpatients

MIAMI, Aug. 30, 2021 (GLOBE NEWSWIRE) -- **OPKO Health, Inc. (NASDAQ: OPK)** announces the completion of enrollment in its Phase 2 trial with RAYALDEE® as a treatment for mild-to-moderate COVID-19. The U.S. trial, "A Randomized, Double-Blind Placebo-Controlled Study to Evaluate the Safety and Efficacy of **R**AYALDEE (calcifediol) **E**xtended-relea**s**e **C**aps**u**l**e**s to Treat Symptomatic Patients Infected with SARS-CoV-2 (**REsCue**)," was expected to enroll approximately 160 subjects, including some with stage 3 or 4 chronic kidney disease (CKD) who are at higher risk for developing more severe illness. Final enrollment reached 171 subjects and topline data are expected later this year.

The REsCue trial randomized symptomatic COVID-19 outpatients in a 1:1 ratio to 4 weeks of treatment with RAYALDEE or placebo and a 2-week follow-up. Dosing with RAYALDEE begins with 300 mcg per day on Days 1, 2 and 3 followed by 60 mcg per day on Days 4 through 27. This dosing regimen is modelled to raise serum total 25-hydroxyvitamin D (25D) within the range of 50-100 ng/mL. The trial's primary efficacy endpoints are attainment of the targeted 25D level and time to resolution of COVID-19 symptoms. Secondary endpoints include incidence of emergency room or urgent care visits, oxygen saturation below 94%, need for and duration of hospitalization, requirement for mechanical ventilation, mortality rate and severity and duration of illness evidenced by quality-of-life and biochemical measures. More information about this trial is available on ClinicalTrials.gov.

About RAYALDEE

RAYALDEE is an extended-release oral formulation of calcifediol, a prohormone of calcitriol, the active form of vitamin D_3. The product is the first and only medicine approved by the U.S. Food and Drug Administration (FDA) for raising serum total 25D and lowering blood levels of intact parathyroid hormone (iPTH). RAYALDEE, approved to treat secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 CKD and vitamin D insufficiency, was launched in the U.S. in November 2016.

About OPKO Health, Inc.

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit 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, includingthe expected benefits of RAYALDEE, whether and when we will complete the clinical study contemplated for RAYALDEE and whether final study data will be positive, our ability to commercialize RAYALDEE for COVID-19 patients, whether RAYALDEE is capable of treating patients with COVID-19 including whether RAYALDEE could impact the SARS-CoV-2 virus or cytokine storm, or have any impact on the severity of the disease or that it will effectively raise and maintain serum total 25D consistently at or above 50ng/mL, as well as other non-historical statements about our expectations, beliefs or intentions regarding our technologies and products, 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 the risks that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, and 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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