Data Supporting Once-Weekly Dosing of hGH-CTP in Growth Hormone Deficient Pediatric Population to be Presented as a Late Breaking Presentation at the European Society of Paediatric Endocrinology Conference

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE: OPK), today announced that the abstract “Top Line Results of Once-Weekly, CTP-Modified Human Growth Hormone (MOD-4023): Phase 2 Dose Finding Study in Children with Growth Hormone Deficiency (GHD)" has been selected for late breaking oral presentation at the 53rd Annual Meeting of the European Society of Paediatric Endocrinology (ESPE) on September 20, 2014 in Dublin, Ireland. OPKO will present six month efficacy, safety, pharmacokinetic and pharmacodynamics data from the company's advanced phase 2 trial for its long acting human growth hormone hGH-CTP (MOD-4023) in growth hormone deficient pediatric subjects.

In addition, OPKO’s posters to be presented during the conference have been recognized for outstanding advancement by ESPE and will introduce additional data, as well as analytical characteristics of hGH-CTP in preparation for the planned pediatric phase 3 study.

The data to be presented include results from the company’s phase 2 trial, a one year dose finding study administering hGH-CTP to growth hormone deficient children once a week using daily hGH as a comparator. The data from this study supported once-weekly dosing for hGH-CTP and also enabled the selection of an appropriate dose to demonstrate non-inferiority compared to daily hGH in the upcoming phase 3 study. hGH-CTP demonstrated a good safety and tolerability profile in this ongoing study.

OPKO presentations include the following:


Session details: FC – Late Breaking; Saturday September 20, 2014 08:45 – 09:45

Poster P1-D3-163 Six month Follow-up Pharmacokinetics and Pharmacodynamics Profile of Once-Weekly, CTP-Modified Human Growth Hormone (MOD-4023): Phase 2 Dose Finding Study in Children with GHD Deficiency

Poster P1-D3-164 CHARACTERIZATION OF MOD-4023 GLYCOSYLATION, A CTP MODIFIED LONG ACTING GROWTH HORMONE IN ADVANCED CLINICAL STAGES

About ESPE Conference

The theme of the meeting is prevention and therapeutic innovations in pediatric endocrinology. Plenary sessions, symposia, meet-the-experts, free communications and poster sessions in an interactive environment with international experts will enable exchange of high quality clinical information and basic science and promote international collaboration in research and clinical practice. visit https://http://www.espe2014.org/

ABOUT OPKO HEALTH

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 http://www.opko.com.

SAFE HARBOR STATEMENT

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 hGH-CTP (MOD-4023), whether OPKO’s clinical trials for adult and pediatric growth hormone deficiency will generate data to demonstrate non-inferiority compared to daily hGH and support marketing approval, whether hGH-CTP will be successfully developed or commercialized, expectations regarding the product, its efficacy, safety and market potential, 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.

OPKO Health, Inc.
Steven D. Rubin or Adam Logal, 305-575-4100

Source: OPKO Health, Inc.