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OPKO Announces Completion of Enrollment in Phase 3 Trial of hGH-CTP in Growth Hormone Deficient Adults

MIAMI--(BUSINESS WIRE)-- **OPKO Health, Inc. (NYSE:OPK)** has completed enrollment in the single pivotal Phase 3 trial of its long acting human growth hormone (hGH-CTP) in growth hormone deficient (GHD) adults.

The trial is designed to evaluate the safety and efficacy of hGH-CTP with a primary endpoint of superiority compared to placebo in decreasing fat mass in adults with GHD. The trial is a randomized, double-blind, placebo-controlled, multi-center, global study in adults with GHD. The study is divided into two treatment periods: a 26-week, double-blind, placebo-controlled period, followed by a 26-week, open-label extension. For further detail on the Phase 3 study, visit <https://clinicaltrials.gov/ct2/show/NCT01909479>.

The study is expected to end toward the second half of 2016; regulatory submission will follow study completion.

OPKO has a world-wide collaboration agreement with Pfizer, Inc. for the development and commercialization of hGH-CTP.

About hGH-CTP

hGH-CTP is a novel, long-acting recombinant human growth hormone analog being developed by OPKO for the treatment of children with growth failure due to inadequate endogenous growth hormone secretion, and adults with growth hormone deficiency (GHD) of either childhood or adult-onset etiology. hGH-CTP is intended to reduce the burden of daily injection therapy.

OPKO's proprietary technology enables elongation of a therapeutic protein's half-life without the use of polymers, encapsulation techniques, or nanoparticles. This technology is based on a natural peptide, the C-terminal peptide (CTP) of the beta chain of human chorionic gonadotropin (hCG). hGH-CTP has been granted orphan drug designation in the U.S. and Europe for both adults and children with growth hormone deficiency.

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 timing of study completion, whether OPKO's clinical trials for adult and pediatric growth hormone deficiency will generate data to support marketing approval, whether study results will demonstrate non-inferiority compared to daily hGH, whether hGH-CTP will be successfully developed or commercialized, expectations regarding the product and its 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, litigation, and the success of our collaboration on hGH-CTP with Pfizer, Inc. 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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