Two Reports on hGH-CTP Pediatric Phase 2 Clinical Data Accepted for Oral Presentation at the 54th Annual Meeting of the European Society for Paediatric Endocrinology (ESPE conference)

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK), announced that additional data from OPKO’s hGH-CTP pediatric Phase 2 clinical trials summarized in two abstracts entitled, “12 month Safety and efficacy of a weekly long-acting growth hormone (GH, MOD-4023) compared to daily recombinant human GH (rh)GH) therapy in pre-pubertal growth hormone deficient children; Phase 2 study – Study CP-4-004 Summary” and “Pharmacokinetic (PK) and Pharmacodynamics (PD) Modeling of MOD 4023 (a long-acting human growth hormone (hGH)) in Growth Hormone Deficient (GHD) Children” has been selected for oral presentation at the upcoming 54th Annual Meeting of the European Society for Paediatric Endocrinology taking place in Barcelona, Spain from October 1-3.

The data to be presented include results for 52 patients completing twelve months of weekly treatment with hGH-CTP. This phase 2 study was a one year, dose finding study administering hGH-CTP to growth hormone deficient children once a week using Genotropin® administered daily as a comparator arm. The twelve months data confirm comparable response of hGH-CTP to Genotropin® injected daily as reflected by the twelve months serum insulin-like growth factor-1 standard deviation score (IGF-1SDS) profile, annual height velocity (HV), height velocity standard deviation score (HV SDS) and safety profile. The data affirm the selection of an optimal dose that would be used to demonstrate non-inferiority compared to daily administered hGH in the upcoming phase 3 study.

OPKO oral presentations will be held at the Growth-promoting therapies session on Saturday, October 3, 2015 at 9:55 AM and 10:05 AM.

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, whether OPKO's clinical trials for adult and pediatric growth hormone deficiency will generate data to support marketing approval, whether the data affirm the selection of an optimal dose, whether hGH-CTP will be successfully developed or commercialized, expectations regarding the product and its market potential, whether hGH-CTP will provide a comparable response to Genotropin®, 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.


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