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# **OPKO Health Announces Dosing of First Subject in Phase 1 Clinical Study of a Long-Acting Oxyntomodulin for the Treatment of Obesity and Type II Diabetes**

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK) today announced dosing of the first subject in a Phase 1 single dose escalation study evaluating the safety and pharmacokinetics of a long-acting Oxyntomodulin (MOD-6031) in healthy, overweight or obese subjects. The study is intended to enroll 40 subjects in Israel.

Oxyntomodulin is a peptide hormone that acts as a dual GLP-1/Glucagon receptor agonist, with the potential to promote weight loss while improving glycemic control. Oxyntomodulin has been shown to increase energy expenditure, while reducing food intake and body weight, although its clinical utility is limited by its short circulating half-life. OPKO's MOD-6031 has been designed, using a proprietary bi-functional hydrolysable linker, as a long-acting version of Oxyntomodulin for the treatment of Type II Diabetes and obesity, and is intended to reduce the required dosage frequency by prolonging the half-life, while improving the hormone's pharmacokinetics and pharmacodynamics.

## **About OPKO Health, Inc.**

OPKO Health, Inc. 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 420-person sales force 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™, a treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency (March 29, 2016 PDUFA date) and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO and NDA filed for IV formulation). Our biologics business includes hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), and a long-acting Factor VIIa drug for hemophilia (entering Phase 2a). We also have production and distribution assets worldwide, multiple strategic investments and an active business development strategy. More information is available at [www.opko.com](http://www.opko.com).

## **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), regarding product development efforts and other non-historical facts about our expectations, beliefs or intentions regarding our business, technologies and products, financial condition, strategies or prospects, including statements regarding our expectations about our long-acting Oxyntomodulin, expectations about market potential for Oxyntomodulin, whether we will be able to

successfully develop, obtain approval for and launch sales of Oxyntomodulin, and the expected completion dates for our trials. 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 risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, including the risks that clinical trials for Oxyntomodulin may not be successful or achieve the expected results or effectiveness, and may not generate data that would support the approval or marketing of this product for the indications being studied, that others may develop products which are superior to Oxyntomodulin, and that Oxyntomodulin may not have advantages or prove to be superior over presently marketed products. 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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