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# OPKO Health Announces the Start of Phase 3 Clinical Trials of Rolapitant for the Prevention of CINV

**Rolapitant is a Neurokinin-1 (NK-1) Receptor Antagonist in Development for Chemotherapy Induced Nausea and Vomiting (CINV)**

**Rolapitant Will Be Developed and Commercialized by TESARO Under License from OPKO**

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE: OPK) today announced that the Phase 3 clinical program for rolapitant is currently enrolling patients. This global program consists of two randomized, double-blind and placebo controlled clinical trials evaluating the efficacy of a single 200mg oral dose of rolapitant in patients receiving highly emetogenic chemotherapy, or HEC, and one clinical trial evaluating the efficacy of a single 200mg oral dose of rolapitant in patients receiving moderately emetogenic chemotherapy, or MEC. Approximately 2,400 cancer patients will participate.

Each of the HEC clinical trials consist of approximately 530 patients and is focused on evaluating rolapitant plus the standard of care compared with placebo plus the standard of care. The MEC clinical trial consists of approximately 1,350 patients and is focused on evaluating rolapitant plus the standard of care compared with placebo plus the standard of care. In each of the Phase 3 clinical trials the standard of care consists of a 5-HT3 receptor antagonist in combination with the corticosteroid dexamethasone.

The patients in these clinical trials are being evaluated for evidence of an improvement in control of nausea and vomiting during the acute (0 – 24 hours), delayed (24 – 120 hours) and overall (0 – 120 hours) time periods post administration of chemotherapy. The primary outcome of each trial will be based on complete response (defined as no emetic episodes and no use of rescue medication) in the delayed phase. Additional outcome measures include complete response for other time points, the incidence and severity of nausea, and safety and tolerability. Results from each of the clinical trials are anticipated in the second half of 2013.

**About Rolapitant**

Rolapitant, a potent and selective neurokinin-1 (NK-1) receptor antagonist with an extended plasma half-life, is currently in Phase 3 clinical testing for prevention of chemotherapy induced nausea and vomiting (CINV). Phase 2 testing in cancer patients treated with highly emetogenic chemotherapy demonstrated promising five-day activity in CINV prevention following the administration of a single dose. The safety and tolerability of single and repeat doses of rolapitant has been assessed in over 1,000 subjects. Rolapitant is an investigational agent and has not been approved by regulatory agencies.

**About Chemotherapy Induced Nausea and Vomiting (CINV)**

CINV, if not prevented by prophylaxis, has the potential to afflict up to 90% of cancer patients undergoing chemotherapy, depending upon the type of chemotherapy administered, the dosing schedule of the chemotherapy and the patients' age and gender, among other predisposing factors. Prolonged nausea and vomiting may result in unwanted weight loss, dehydration and malnutrition as well as hospitalization. If not prevented, CINV may result in a delay or even discontinuation of chemotherapy treatment.

NK-1 receptors are highly concentrated in the brain and bind the neurokinin substance P. Activation of NK-1 receptors plays a central role in nausea and vomiting induced by emetogenic stimuli, including certain cancer chemotherapies. NK-1 receptor antagonists have been demonstrated to improve the management of nausea and vomiting experienced by cancer patients undergoing chemotherapy.

**About OPKO Health, Inc.**

OPKO is a multi-national biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging its discovery, development and commercialization expertise and novel and proprietary technologies.

*Forward Looking Statements:*

*Any statements that are not historical facts contained in this release are "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 expectations about the enrollment in and outcome of the clinical trials for rolapitant, the expected timing thereof, TESARO's ability to successfully develop and commercialize rolapitant for CINV, and the expected benefits of rolapitant in managing the nausea and vomiting experienced by cancer patients undergoing chemotherapy. 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 OPKO's filings with the Securities and Exchange Commission, and risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments, including that enrollment of patients in the rolapitant trials may not be successful, that the trials may not be completed on a timely basis or at all, that rolapitant may fail, may not achieve the expected results or effectiveness and may not generate data that would support approval or marketing of the product 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 OPKO does 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.

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