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OPKO Licensee TESARO Submits New Drug Application for Rolapitant

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK), reported that its licensee, TESARO, Inc. (Nasdaq:TSRO), has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for approval of oral rolapitant, an investigational neurokinin-1 (NK-1) receptor antagonist in development for the prevention of chemotherapy-induced nausea and vomiting (CINV).

This NDA is supported by data from four controlled studies covering a spectrum of patients receiving chemotherapy that commonly causes nausea and vomiting. The top-line results of three of the Phase 3 studies were previously announced by TESARO and were presented in detail at the American Society for Clinical Oncology (ASCO) annual meeting in June 2014.

Under the terms of OPKO's agreement with TESARO, OPKO is eligible to receive payments of up to $121 million, including up-front and additional payments based on regulatory and commercialization milestones, including acceptance by FDA of the NDA. OPKO will receive double digit tiered-royalties on sales of rolapitant. In addition, TESARO and OPKO will share future profits from the commercialization of rolapitant in Japan, and OPKO will have an option to market the products in Latin America.

"We are pleased by the very professional work of the TESARO team in completing the studies required to file the NDA. OPKO's other internal projects are progressing as planned and we are anxious to introduce these important new products to the market as rapidly as possible," commented Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO.

About Rolapitant

Rolapitant is a potent and selective neurokinin-1 (NK-1) receptor antagonist with an extended plasma half-life that is being developed for the prevention of chemotherapy-induced nausea and vomiting (CINV). 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. The safety and tolerability of single and repeat doses of rolapitant have been assessed in more than 2,500 healthy volunteers and patients. Rolapitant is being developed both in oral and intravenous formulations. TESARO licensed exclusive rights for the development, manufacture, commercialization and distribution of rolapitant from OPKO.

About Chemotherapy-Induced Nausea and Vomiting (CINV)

CINV is estimated to afflict over 70% of cancer patients undergoing chemotherapy and, if not prevented, may possibly result in a delay or even discontinuation of chemotherapy treatment. Prolonged nausea and vomiting may result in unwanted weight loss, dehydration

and malnutrition, as well as hospitalization.

About OPKO Health, Inc.

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

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 rolapitant, whether rolapitant will ever be successfully developed or commercialized, the expected timing of approval of the product, Tesaro's ability to market and sell rolapitant, 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 Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and in our other 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, that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results, that rolapitant and/or any of our compounds or diagnostic products under development may fail, may not achieve the expected results or effectiveness and may not generate data that would support the approval or marketing of products for the indications being studied or for other indications, that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products 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 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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