May 12, 2014

OPKO Licensee TESARO Announces Successful Achievement of Primary and All Secondary Endpoints in Third and Final Phase 3 Trial of Rolapitant

- **Achieved Primary Endpoint of Complete Response (CR) in the Delayed Period (24 to 120 Hours) Following Initiation of Chemotherapy**
- **Achieved Key Secondary Endpoints of CR in the Acute and Overall Periods**
- **Achieved All Secondary Endpoints, Including No Significant Nausea**
- **Adverse Event Profile Consistent with Earlier Clinical Trials**
- **New Drug Application (NDA) Submission to U.S. FDA On Track for Mid-2014**

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK), reported that its licensee, TESARO, Inc. (Nasdaq:TSRO), announced positive top-line results from the third and final Phase 3 trial of rolapitant, an investigational neurokinin-1 (NK-1) receptor antagonist in development for the prevention of chemotherapy-induced nausea and vomiting (CINV). The rolapitant arm in this trial, which enrolled patients receiving cisplatin-based, highly emetogenic chemotherapy (HEC), successfully achieved statistical significance over the standard therapy arm for the primary and all secondary endpoints. The adverse event profile for rolapitant remains consistent with that seen in previous clinical studies.

The third Phase 3 study of rolapitant was an international, multicenter, randomized, double-blind, active-controlled study that enrolled 532 cancer patients receiving cisplatin-based chemotherapy regimens at a dose equal to or greater than 60 mg/m^2. Patients were randomized to receive either control, which consisted of a 5-HT$_3$ receptor antagonist plus dexamethasone, or 200 milligrams of oral rolapitant plus control. The rolapitant arm in this study successfully achieved statistical significance over the control arm for the primary endpoint of complete response (CR) in the delayed phase of CINV. In addition, the rolapitant arm also successfully achieved statistical significance over the control arm for the key secondary endpoints of CR in the acute (0 to 24 hour) and overall (0 to 120 hour) phases of CINV, for the secondary endpoint of no significant nausea, and for all other secondary endpoints.

Safety and tolerability data for patients who received rolapitant were similar to the results for those who received control, and were consistent with earlier clinical studies. The most frequently observed adverse events were balanced across treatment arms and included fatigue, constipation and loss of appetite.

TESARO continues preparations in support of a submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in mid-2014. The oral rolapitant NDA will include data from one Phase 3 study in patients receiving moderately emetogenic chemotherapy (MEC), in addition to one Phase 2 and two Phase 3 trials in patients receiving

cisplatin-based, highly emetogenic chemotherapy (HEC), including the trial announced today. The top-line results of the Phase 3 trial in MEC and the prior Phase 3 trial in HEC were previously announced by TESARO in December 2013.

Rolapitant is an investigational agent and, as such, has not been approved by the U.S. FDA or any regulatory agencies.

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 TESARO, Inc.

TESARO is an oncology-focused biopharmaceutical company dedicated to improving the lives of cancer patients by acquiring, developing and commercializing safer and more effective therapeutics.

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 an NDA, 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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Source: OPKO Health, Inc.