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OPKO Health Licensee TESARO Announces FDA Approval of VARUBI® IV for Delayed Nausea and Vomiting Associated with Chemotherapy

OPKO to receive tiered double-digit royalties on product sales

MIAMI, Oct. 26, 2017 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ:OPK) announces that its licensee, TESARO, Inc. (Nasdaq:TSRO), received U.S. Food and Drug Administration (FDA) approval for VARUBI® (rolapitant) IV in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Delayed nausea and vomiting can occur anytime between 25 and 120 hours following chemotherapy, and is often extremely debilitating.

TESARO licensed exclusive rights for the development, manufacture, commercialization, and distribution of VARUBI (rolapitant) from OPKO Health in December 2010. TESARO previously launched an oral version of VARUBI in November 2015. OPKO Health will receive tiered double-digit royalties on sales of VARUBI IV. In addition, OPKO Health is eligible to receive additional commercial milestone payments of up to \$85 million upon achievement of certain sales thresholds. TESARO is expected to launch VARUBI IV in November 2017.

“We are especially pleased that our partner, TESARO, has received FDA approval for VARUBI IV. This is particularly important as IV treatments for chemotherapy induced nausea and vomiting account for 90% of the market. We look forward to TESARO’s continued success in commercializing the VARUBI product line,” said Philip Frost, M.D., Chairman and Chief Executive Officer of OPKO Health.

About VARUBI

VARUBI is a highly selective and competitive antagonist of human substance P/neurokinin 1 (NK-1) receptors, which play an important role in the delayed phase of chemotherapy induced nausea and vomiting (CINV). With a long plasma half-life of approximately seven days, a single dose of VARUBI, as part of an antiemetic regimen, significantly improved complete response (CR) rates in the delayed phase of CINV. Results from three Phase 3 trials of VARUBI oral tablets demonstrated a significant reduction in episodes of vomiting or use of rescue medication during the 25- to 120-hour period following administration of highly emetogenic and moderately emetogenic chemotherapy regimens. In addition, patients who received VARUBI reported experiencing less nausea that interfered with normal daily life and fewer episodes of vomiting or retching over multiple cycles of chemotherapy. Results from a bioequivalence trial demonstrated comparability of the IV and oral formulations of VARUBI.

VARUBI is available by prescription only. Please see full prescribing information, including additional important safety information, available at www.varubirx.com.

About OPKO Health, Inc.

OPKO Health is a diversified healthcare company that seeks to establish industry leading positions in large, rapidly growing markets. Our diagnostics business includes BioReference Laboratories, the nation's third largest clinical laboratory with a core genetic testing business and a 400 person sales and marketing team 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, an FDA approved treatment for SHPT in stage 3-4 CKD patients with vitamin D insufficiency (launched in November 2016), VARUBI® for chemotherapy induced nausea and vomiting (oral formulation launched by partner TESARO and IV formulation pending FDA approval), OPK88003, a once weekly oxyntomodulin for type 2 diabetes and obesity that is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and OPK88004, a selective androgen receptor modulator being developed for benign prostatic hyperplasia and other urologic and metabolic conditions. 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 in 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.

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), regarding product development efforts and other non-historical facts about our expectations, beliefs or intentions regarding our business, and products, financial condition, strategies or prospects, including statements regarding expectations about VARUBI and the success of the collaboration and licensing agreement with TESARO, whether TESARO will successfully launch and commercialize VARUBI IV, whether royalty or commercial milestone obligations to OPKO will ever be triggered, and the expected market for VARUBI IV. 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, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable products and treatments, including the risks that others may develop products which are superior to VARUBI IV, and that VARUBI IV 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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