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LeaderMed Group and OPKO Health Form Joint Venture to Develop and Commercialize Oxyntomodulin and Factor VIIa-CTP in China and Other Asian Territories

SHANGHAI and MIAMI, Sept. 14, 2021 (GLOBE NEWSWIRE) -- LeaderMed Health Group Limited, a pharmaceutical development company with operations based in Asia, and OPKO Health, Inc. (NASDAQ: OPK), a diversified healthcare company focused on diagnostics and pharmaceuticals, announce the formation of a joint venture to develop, manufacture and commercialize two of OPKO's clinical stage, long-acting drug products in Greater China and eight other Asian territories.

Under the terms of the agreements, OPKO will grant the joint venture exclusive rights to develop, manufacture and commercialize (a) OPK88003, an oxyntomodulin analog being developed for the treatment of obesity and diabetes, and (b) Factor VIIa-CTP, a novel long-acting coagulation factor being developed to treat hemophilia, in exchange for a 47% ownership interest in the joint venture. In addition, OPKO will receive an upfront payment of \$1 million and will be reimbursed for clinical trial material and technical support it provides the joint venture.

LeaderMed will be responsible for funding the joint venture's operations, development and commercialization efforts and will, with its syndicate partners, initially invest \$11 million in exchange for a 53% ownership interest. OPKO retains full rights to oxyntomodulin and Factor VIIa-CTP in all other geographies.

"Through this joint venture, we have an opportunity to extend the global availability of two of our novel long-acting development products and to establish a presence in China in partnership with collaborators who have significant experience and deep knowledge of the Asian biopharmaceutical opportunity," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO.

"LeaderMed Group is an innovative pharmaceutical development company with its own pipeline of licensed products. Our capabilities include an experienced management team with demonstrated success in bringing biopharmaceutical and pharmaceutical products to market in China and globally, cGMP facilities to manufacture clinical-grade products, and a corporate charter that acknowledges and protects client IP. We are excited about the opportunity to expeditiously deliver a novel and superior treatment for obesity and diabetes to hundreds of millions of patients in China and Asia, as well as a treatment for hemophilia, an orphan indication," added Dr. Joanne Jiang, Chief Executive Officer of LeaderMed Group and architect of the joint venture.

About Oxyntomodulin

Oxyntomodulin is a naturally occurring hormone produced in the colon that binds the GLP-1 and glucagon receptors, regulating both blood glucose appetite and lipid metabolism. OPKO Health is developing OPK88003, a long-acting, once-weekly oxyntomodulin analog for the treatment of type 2 diabetes and obesity. OPK88003 has been successfully studied in two Phase 2 clinical trials enrolling type 2 diabetes patients, studying weight loss and reduction in glycosylated hemoglobin (HbA1c or A1c), a marker of sugar metabolism. Driven by the LeaderMed-OPKO joint venture, it is positioned to be the first dual-targeted drug approved for diabetes and obesity in the Chinese and Asia markets.

About Factor VIIa-CTP

Factor VIIa-CTP is a novel, long-acting recombinant Factor VIIa utilizing OPKO's proprietary technology to extend its circulatory half-life without the use of polymers, encapsulation techniques or nanoparticles. The technology is based on a naturally occurring peptide, the C-terminal peptide (CTP) of the beta chain of human chorionic gonadotropin. The CTP technology is also used in OPKO's hGH-CTP (somatrogen), a long-acting recombinant human growth hormone product that successfully completed Phase 3 clinical trials in children with growth hormone deficiency. hGH-CTP has been submitted for approval in the United States, Europe and Japan and is partnered with Pfizer for global commercialization. Factor VIIa-CTP has been granted orphan drug designation in the U.S. and Europe.

In China, hemophilia was designated as a rare disease in 2018. LeaderMed expects to seek fast regulatory approval for Factor VIIa-CTP through a special national rare disease channel.

About LeaderMed Group

The LeaderMed Group is a pharmaceutical development company with operations in Asia and a professional team in Greater China and Asia with extensive new drug development experience and successful case histories.

About OPKO Health, Inc.

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit www.opko.com.

Cautionary Statement Regarding 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), 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 product development efforts as well as other non-historical statements about our expectations, products, beliefs or intentions regarding our business, financial condition, strategies or prospects including statements regarding expectations about the success of the collaboration and joint venture with LeaderMed, whether the joint venture will successfully develop, obtain regulatory approval for, launch or commercialize either oxyntomodulin or Factor VIIa-CTP, and the expected market for the products in Greater China and Asia. 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 under the heading "Risk Factors" in our other

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. 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.

OPKO Contacts:

LHA Investor Relations

Yvonne Briggs, 310-691-7100

ybriggs@lhai.com

or

Bruce Voss, 310-691-7100

bvoss@lhai.com



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