

OPKO to Present New Data at International Society on Thrombosis and Haemostasis (ISTH) 2015 Congress on Its Long-Acting Clotting Factor VIIa

New Preclinical Data further demonstrate the safety and efficacy of MOD-5014 (FVIIa – CTP) for both Intravenous and Subcutaneous Administration

MIAMI--(BUSINESS WIRE)-- OPKO Health, Inc. (NYSE:OPK), today announced that the company will present new data on its long-acting clotting Factor VIIa-CTP (MOD-5014) at the International Society on Thrombosis and Haemostasis (ISTH) 2015 Congress being held June 20-25, 2015 in Toronto, Ontario, Canada. OPKO's Factor VIIa-CTP is a next-generation investigational therapy currently in a Phase 2a U.S. based study for the treatment of patients with hemophilia.

Currently, Factor VIIa therapy is available only as an intravenous (IV) formulation, which requires frequent multiple infusions to treat a bleeding episode due to Factor VIIa's short half-life. In addition, the requirement for multiple weekly infusions can be onerous for patients interested in preventative prophylactic treatment of the disease, especially children.

Previously presented pre-clinical data utilizing both intravenous and subcutaneous administration in hemophilic animal models demonstrated the long acting properties of Factor VIIa-CTP as compared to commercial rFVIIa, with superior half-life, reduced bleeding and increased survival for a significantly longer period.

Five abstracts were accepted for presentation at the upcoming ISTH conference. The following abstracts will be presented from 5:00-7:00 p.m. local time on June 23-24th.

PO062-TUE: EX-VIVO AND IN-VITRO COMPARATIVE ASSESSMENT OF MOD-5014 (FACTOR VIIA-CTP), A NOVEL LONG-ACTING COAGULATION FACTOR TO RECOMBINANT FVIIA

PO550-TUE: EFFECT OF A CARBOXY-TERMINAL PEPTIDE (CTP) ON FACTOR VIIA ACTIVITY

PO594-WED: COMPREHENSIVE ASSESSMENT OF THE SAFETY AND EFFICACY OF FACTOR VIIA-CTP SUPPORTING PHASE 2A STUDY

PO595-WED: FACTOR VIIA-CTP, A LONG-ACTING COAGULATION FACTOR PROPOSING A NOVEL SUBCUTANEOUS (SC) ROUTE OF ADMINISTRATION FOR PROPHYLACTIC TREATMENT –EFFICACY AND SAFETY IN PREPARATION FOR FIRST IN HUMAN STUDY **PO048-WED**: ASSESSMENT OF MOD-5014, A LONG ACTING FVIIA, PHARMACOKINETIC, PHARMACODYNAMICS AND CORRECTION OF HEMOPHILIC COAGULOPATHY IN DOGS WITH HEMOPHILIA A AS PART OF THE PREPARATION FOR FIRST IN HUMAN STUDY

About Hemophilia

Patients with hemophilia do not produce adequate amounts of the clotting factors that are necessary for effective blood clotting. In severe hemophiliacs even a minor injury can result in blood loss that may continue for days or weeks, with the potential for debilitating permanent damage to joints and other organs and premature death. According to the World Health Organization, more than 400,000 people worldwide have hemophilia. Commercially available recombinant clotting factors have enabled many hemophiliacs to live near-normal lives, but frequent infusions and/or blood transfusions may be required.

Factor VIIa-CTP has been granted orphan drug designation in the U.S. and Europe.

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 <u>http://www.opko.com</u>.

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, technologies and products, financial condition, strategies or prospects, including statements regarding our expectations about our long-acting version of clotting Factor VIIa (Factor VIIa-CTP) for the treatment of bleeding episodes in patients with hemophilia A or B with inhibitors to Factor VIII or Factor IX, whether Factor VIIa-CTP has the potential for substantial improvement of the quality of life of patients, via both IV and subcutaneous (SC) administration, whether Factor VIIa-CTP will be able to be administered subcutaneously using a simple injection and allow children and adults with hemophilia to easily self-administer the drug at home on a prophylactic basis, whether we will be in a position to be first to market with a longer acting Factor VIIa product, expectations about market potential for Factor VIIa-CTP, whether we will be able to successfully develop, obtain approval for and launch sales of the Factor VIIa-CTP, and the expected completion dates for our trials. 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 filings with the Securities and Exchange Commission, as well as risks inherent in funding, developing and obtaining regulatory approvals of new, commerciallyviable and competitive products and treatments, including the risks that clinical trials for Factor VIIa-CTP may not be successful or achieve the expected results or effectiveness, and may not generate data that would support the approval or marketing of this product for the indications being studied, that others may develop products which are superior to Factor VIIa-CTP, and that Factor VIIa-CTP 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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OPKO Health, Inc. Steven D. Rubin, 305-575-4100 or Adam Logal, 305-575-4100

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