Developing Drugs to Treat Metabolic Syndrome

XORTX Pharma Corp. is a cardiovascular therapeutics company focused on advancing the clinical use of uric-acid-lowering drugs to treat the newly discovered health-related consequences of hyperuricemia, or chronically increased serum uric acid. Hyperuricemia is associated with high blood pressure, obesity, insulin resistance, metabolic syndrome, diabetes, and renal and cardiovascular disease, recent studies have shown. The most common causes of hyperuricemia are dietary: overconsumption of purine- and fructose-rich foods. Excessive consumption of organ meats, certain seafood, alcohol and fructose are particularly problematic.

Technology

XORTX is developing two products that lower uric acid, based on technology developed at the University of Florida. The first, “Allo-Pure”, is a liquid dosing formulation to treat high blood pressure and obesity, and improve vascular health. Second-generation formulations will focus on preventing insulin resistance, decreasing blood pressure and preventing diabetes among adolescents and young adults. Allo-Pure is composed of allopurinol and other nutrition and physiology-supporting components that are safe for obese adolescent patients who have high blood pressure and hyperuricemia. The second product, “Oxy-Retic,” is designed for these same patients. About 30 percent of patients who suffer from high blood pressure and high serum uric acid cannot take the preferred anti-hypertensive therapy, thiazide diuretics. Oxy-Retic overcomes this problem. It is an improved combination form of thiazide that permits a synergistic and simultaneous reduction in serum uric acid (anti-hypertensive), hyperlipidemia (too much fat in the blood), hypercholesteremia (high LDL cholesterol) and thiazide use. The dual action of Oxy-Retic will synergistically allow patients to excrete more uric acid in their urine, while blocking the production of uric acid in the body.

Market Potential

Excess uric acid in the blood (hyperuricemia) is a common problem, affecting as much as 21 percent of the U.S. population – approximately 43.3 million American adults. Historically, high uric acid has only been treated when it causes painful, inflamed joints – a common symptom of gout. Groundbreaking research now suggests that uncontrolled hyperuricemia predisposes patients not only to gout, but a wide range of previously undescribed health consequences, including metabolic and cardiovascular conditions. Two recent clinical trials in adolescent hypertension strongly support the concept that lowering uric acid levels may result in substantial health benefits, particularly among obese adolescents and young adults with hypertension, insulin resistance and renal insufficiency. Solid basic scientific evidence further suggests that decreasing serum uric acid to below 5.5 mg/dl will be an important future treatment for metabolic syndrome, and prevention of diabetes and renal nephropathy. An estimated 3.1 million obese adolescents and 50 million members of the general population have hypertension. In the United States, an estimated 35 million people suffer from insulin resistance, 50 million have metabolic syndrome, and 21 million have diabetes. The economic burden is estimated at $640 billion for obesity, $85 billion for hypertension and $198 billion for diabetes.
Strategy

XORTX will seek strategic partnerships with large pharmaceutical companies that have marketing strength in pediatrics, pediatric hypertension, insulin resistance, metabolic syndrome and diabetes. The primary goal is to achieve co-development or acquisition of the products to promote advancement through Phase III development, FDA approval and successful market launch. The company is currently scaling up regulatory and clinical staff to prepare for their anticipated upcoming Phase II/III clinical trial to evaluate the benefit of uric acid lowering in patients with hypertension and insulin resistance. The company plans to market programs with pharmaceutical partners via licensing or acquisition deals.

Management Team

Allen Davidoff, Ph.D., President and CEO
Dr. Davidoff has more than a decade of drug-development experience in clinical and regulatory settings. He co-founded Stem Cell Therapeutics Corp, a public Canadian company, where he worked as Chief Scientific Officer and VP of Product Development for seven years. Prior to that Dr. Davidoff held the position of Senior Scientist and Head of Pharmacology at Cardiome Pharma, a cardiovascular drug-development company based in Vancouver, where Dr. Davidoff gained valuable senior management experience in pharmaceutical research and development.

Grace Jung, Ph.D., Director Manufacturing and Synthetic Chemistry
Grace Jung, PhD (21 years of experience in drug discovery and development) was formerly Senior Director of Research (Chemistry) at Cardiome. During the 14 years at Cardiome, she led the chemistry team in the discovery of antiarrhythmic vernakalant and in process research efforts to devise a scalable manufacturing route for vernakalant. Before joining Cardiome, Grace spent 7 years at Boehringer Ingelheim (Laval, QC, Canada), where she was a medicinal chemist working on renin inhibitors as antihypertensive drugs.

Brian Mangal, CTO
Brian Mangal, M.Sc. (12 years of clinical development experience), was formerly Director Biostatistics at Cardiome. Clinical development experience includes design, analysis and reporting of over 50 clinical trials, three FDA submissions, one TPD submission, a successful EMEA submission and numerous interactions with regulatory authorities, including participation in a successful advisory panel meeting for Vernakalant.

Alan Moore, Ph.D., Founding Board Member, Executive Consultant: Clinical and Regulatory Affairs
Dr. Alan F. Moore, Ph.D. has extensive clinical development experience and 23 years of senior management experience in pharmaceutical R&D with P&G. During his esteemed career, he has completed 11 investigational new drug ("IND") applications or supplemental IND’s, 15 Phase I studies, 12 Phase II studies, seven Phase III studies and two new drug applications. He was most recently CEO of BetaStem Inc.

Contact Information

XORTX Pharma Corp.
Dr. Allen Davidoff, President and CEO
403-607-2621
Allen.davidoff@gmail.com