



Pharsight to Work with Critical Path Institute's Polycystic Kidney Disease Consortium on Disease Progression Modeling

Consortium Includes Academic, Regulatory, and Industry Experts in Effort to Accelerate Pace of Medical Product Development

ST. LOUIS, MO – September 7, 2011 – Pharsight, a market-leading provider of software and scientific consulting services to improve productivity and decision-making in clinical drug development, has announced they will be working with Critical Path Institute (C-Path)'s Polycystic Kidney Disease (PKD) Consortium to create and study quantitative models of disease progression in patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD).

The PKD Consortium is a successful collaboration between C-Path, the PKD Foundation, Clinical Data Interchange Standards Consortium (CDISC), and four leading academic medical centers (Tufts University, University of Colorado - Denver, Emory University, and Mayo Clinic). The Consortium is led by C-Path and funded through a grant from the PKD Foundation and philanthropic donations. Additionally, a representative from the U.S. Food and Drug Administration (FDA) serves as an active advisor to the Consortium.

"ADPKD is a debilitating genetic disease affecting more than 600,000 Americans and 12 million people worldwide for which there is currently no known cure or effective treatment," said Ronald Perrone, MD, Co-Director of the PKD Consortium and Professor of Medicine at Tufts University School of Medicine.

"This is a very exciting project that leverages the power of collaboration," said Eslie Dennis, MD, FCP, Executive Director of the PKD Consortium at C-Path. "Traditional endpoints of renal function only show changes very late in the course of the disease, making it difficult to assess the effectiveness of new medications. There is critical need for a biomarker that will assess disease progression at an earlier stage when patients may be more likely to respond to new therapies."

"We are very pleased about this significant scientific partnership with Pharsight," added Jill Panetta, PhD, Interim Chief Executive Officer for the PKD Foundation. "The PKD Consortium has brought together impressive resources in support of our mission to promote research that will lead to the discovery of treatments for PKD and improve the lives of all it affects."



The primary goals of the PKD Consortium are to develop CDISC research data standards for PKD and to use clinical data from PKD patients collected over many years through patient registries and clinical trials to support the FDA-qualification of an imaging biomarker, Total Kidney Volume (TKV), as an endpoint in drug development trials.

Scientists and physicians from Pharsight and the PKD Consortium will use the data collected to develop a quantitative disease progression model that will evaluate the relationship between TKV and the known complications of ADPKD, including rate of loss of kidney function, development of end-stage renal disease, and mortality. These analyses will be used to support the regulatory qualification of TKV as an accepted measure for assessing the progression of ADPKD in clinical trials in which new therapies are tested.

“Critical Path Institute is proud to be the facilitator of this ground breaking collaboration to accelerate the pace of drug development for this disease,” said Raymond Woosley, MD, PhD, President and Chief Executive Officer of C-Path. “We welcome the opportunity to work with Pharsight and its team of scientists.”

“Pharsight is honored to join this important and innovative project,” added JF Marier, PhD, FCP, Vice President and Lead Scientist at Pharsight. “We are all committed to the development of a qualified measure that will encourage drug development organizations to test potential new disease-modifying treatments for ADPKD.”

About Pharsight

Pharsight, a Certara™ company, is a market-leading provider of software products and scientific consulting services to help pharmaceutical and biotechnology companies improve their drug development process, regulatory compliance and strategic decision-making. Established in 1995, the company’s goal is to help customers reduce the time, cost and risk of drug development. With more than 1200 customers worldwide, Pharsight products and services are used by all of the world’s top 50 pharmaceutical firms. More information about Pharsight is available at www.pharsight.com.

About Critical Path Institute (C-Path)

An independent, non-profit organization established in 2005 with public and private philanthropic support from the Southern Arizona community, Science Foundation Arizona (SFAz), and the U.S. Food and Drug Administration (FDA),



C-Path is committed to transformational improvement of the drug development process. An international leader in forming collaborations around this mission, C-Path has established first-of-its-kind global partnerships that currently include over 1,000 scientists from government, regulatory agencies, academia, patient advocacy organizations, and thirty major pharmaceutical companies. C-Path is headquartered in Tucson, Arizona, with offices in Phoenix, Arizona, and Rockville, Maryland. More information about C-Path is available at www.c-path.org.

About The PKD Foundation

Polycystic Kidney Disease affects one in 500 people, regardless of gender, age or ethnicity. More than 600,000 Americans and 12.5 million people worldwide suffer from this debilitating genetic disease. The PKD Foundation is the primary research, education and advocacy group working to find a treatment and a cure for Polycystic Kidney Disease. More information about PKD and the PKD Foundation is available at www.pkdcure.org.

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