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THE INTERNATIONAL SERIOUS ADVERSE EVENT CONSORTIUM AND UC SAN DIEGO TO COLLABORATE ON RESEARCH INTO THE GENETICS OF DRUG INDUCED RENAL INJURY

UAB-UCSD O'Brien Center to coordinate an international research network to research the role of genetic variation in drug induced renal injury

Chicago (August XX, 2012) – The International Serious Adverse Events Consortium (iSAEC) announced today it will collaborate with the University of California, San Diego School of Medicine and UC San Diego Skaggs School of Pharmacy and Pharmaceutical Science to research the genetics of drug induced renal injury (DIRI). The iSAEC is a novel, non-profit international research consortium, funded by the global pharmaceutical industry and the Wellcome Trust, to better understand the role genetics plays in drug safety and response. UC San Diego is one of the country's top research universities and has an impressive history of pioneering biomedical and scientific research. The International Drug Induced Renal Injury Consortium (DIRECT) will be supported by the NIH funded O'Brien Center for Acute Kidney Injury Research which is also home to the International Acute Kidney Injury Registry. The O'Brien Center is a collaborative research endeavor between the University of Alabama at Birmingham and the University of California, San Diego.

DIRECT will be co-directed by Ravindra L Mehta, MD, Professor of Clinical Medicine in the Division of Nephrology and Associate Chair for Clinical Research, Department of Medicine, Principal Investigator for the UCSD O'Brien Center; and Linda Awdishu, PharmD, Assistant Clinical Professor of Pharmacy. DIRECT will recruit patients with serious drug induced renal injury reactions, through a collaborative network comprised of 20+ leading clinical research centers from around the world. This collaboration will launch the iSAEC's research into the genetics of drug induced renal injury (DIRI), through a research strategy that focuses on key causal drugs and diverse populations groups that experience this adverse drug reaction.

"Our genetic research points to a strong role of the immune system in these adverse responses." said Arthur L. Holden, Chairman of the iSAEC. "To better understand the full genetic effects contributing to these diseases, we need to develop a large and diverse collection of research subjects, in conjunction with international clinical researchers who share our strong interest and have experience with DIRI reactions. We are thrilled that Drs. Mehta and Awdishu and the O'Brien Center share our commitment to such a large scale international research collaboration. I can think of no better setting for the DIRECT clinical coordinating center and bio-repository than at UC San Diego."

"Our ultimate aim is to develop simple genetic tests so that drug therapy can be personalized and those at risk of these kidney reactions can be prescribed medications safely," said Mehta. "This is a great opportunity to further our research into genetic and molecular basis of Acute Kidney Injury (AKI), while expanding the research network we have developed for AKI. The main aim of the project is to define the genetic risk factors predisposing to DIRI in order to develop strategies for individualization of drug therapy to maximize benefits and minimize harm. International cooperation and scale are vital to enable us to understand these relatively frequent, serious, adverse reactions to certain prescription medicines causing AKI."

About the iSAEC (http://www.saeconsortium.org)

The International Serious Adverse Event Consortium (iSAEC) is a 501(c) organization dedicated to identifying and validating DNA-variants useful in predicting the risk of drug-related serious adverse

events. The Consortium brings together the pharmaceutical industry, regulatory authorities and academic centers to address clinical and scientific issues associated with drug-related serious adverse events. iSAEC partners are providing financial support, in-kind donations, and participation in data collection to the Stage II research. The iSAEC is the only privately-funded international partnership dedicated to studying the genomics of drug induced serious adverse events.

iSAEC Membership and Collaborators
The iSAEC's participants include representatives from the pharmaceutical industry, the scientific community, and government.

- Pharmaceutical industry members are closely involved in all aspects of the Consortium's research, providing ongoing consultation on the development and structure of the Consortium's scientific models, and contributing cohort data and underwriting costs of the iSAEC's research/operations. The iSAEC's Phase 2 funding members include: Abbott, Amgen, AstraZeneca, Daiichi Sankyo, GlaxoSmithKline, Merck, Novartis, Pfizer, Takeda and the Wellcome Trust.
- iSAEC provides researchers with open access to its data through a controlled-access database. Twelve months after genotyping studies are complete, data is released without any patent or intellectual property constraints, allowing for further use and study by interested researchers.

About the UAB-UCSD O'Brien Core Center for Acute Kidney Injury Research (www.obrienaki.org)

The UAB-UCSD O'Brien Core Center for Acute Kidney Injury Research is one of eight centers funded nationwide and is an interdisciplinary center of excellence in AKI-related research. The objective of the Clinical Research Core at UC San Diego is to provide resources to enable clinical investigation in AKI that will advance our understanding of the natural history and pathophysiology of human AKI, ascertain genetic contributions for susceptibility and prognosis of AKI, enhance our diagnostic specificity and expand our preventive and therapeutic approaches for this disorder.

The core leverages existing resources at UAB, UC San Diego and other cores within the O'Brien center to promote the translation of key findings from pre-clinical studies to humans and inform the development of new preclinical models of AKI based on results of clinical studies. A unique aspect of this core is that it provides a resource to enable AKI investigators to perform outstanding systematic genomic and biomarker analyses to support correlation with clinical phenotypes. The core resources also support an educational enrichment program to train investigators in the design and conduct of clinical and pre-clinical research in AKI.

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