iSAE Consortium Ltd.

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THE INTERNATIONAL SERIOUS ADVERSE EVENT CONSORTIUM LAUNCHES A NEW INTERNATIONAL CONSORTIUM (DIRECT) TO RESEARCH THE ROLE GENETICS PLAYS IN DRUG INDUCED RENAL INJURY

The DIRECT (Drug Induced Renal Injury Consortium) Study announces the formation of an international research network of academic sites to enable this vital pharmaco-genetics research.

Chicago, IL (January 11, 2013) – The International Serious Adverse Events Consortium (iSAEC) announced today the launch of a new pharmaco-genetics research effort, the DIRECT Study, to research the role genetics plays in drug induced renal injury (DIRI). As announced last August, the University of California, San Diego School of Medicine and UC San Diego Skaggs School of Pharmacy and Pharmaceutical Science will serve as the international coordinating center for the DIRECT Study. 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.

The DIRECT Study launches the iSAEC's first effort to comprehensively research the genetics of drug induced renal injury (DIRI), through a strategy that focuses on key causal drugs and diverse population groups that have experienced DIRI. The DIRECT Study will recruit thousands of DIRI patients, over a two year period, through a collaborative network comprised of over 25 leading clinical research/nephrology centers from around the world. The research centers participating in the DIRECT consortium include:

- International Renal Institute at San Bortolo Hospital, Vicenza, Italy
- Universitätsklinik für Innere Medizin, Innsbruck, Austria
- VUB University-UZ, Brussels
- University College-Dublin, Ireland
- UCL Centre for Nephrology, Royal Free Hospital, UK
- St James' University Hospital, Leeds, UK
- University of Nottingham, Nottingham, UK
- Guy's & St Thomas Hospital, London, UK
- Newcastle University, Newcastle, UK
- Jacobi Medical Center, NY, NY, USA
- University of Alabama at Birmingham, Birmingham, AL, USA
- UCSD Medical Center, San Diego, CA, USA
- UCSD Children's Hospital, San Diego, CA, USA
- Southeast Renal Research, Chattanooga, TN, USA
- Knoxville Kidney Center, Knoxville, TN, USA
- Cincinnati Children's Hospital, Cincinnati, OH, USA
- St. Peter's Hospital, Albany Medical College, Albany, NY, USA
- Hopital Sacre Coeur & Universite de Montreal, Canada
- Prince of Wales Hospital, University of South Wales, Australia
- University of Los Andes, Santiago, Chile
- Instituto D' Or de Pesquisa e Ensino, Rio de Janeiro, Brazil
- University of San Paulo, San Paulo, Brazil
- Universidad del Valle, Cochabamba, Bolivia
- Peking University First Hospital, Beijing, China
- CARE Hospitals, Banjara, Hyderabad, India
- Postgraduate Institute of Research, Chandigarh, India

Additional centers will be likely be added during the first half of 2013.

“Our genetic research points to a strong role of the immune system in contributing to these rare, but serious adverse responses.” said Arthur L. Holden, Chairman and CEO of the iSAEC. “To better understand the full genetic effects contributing to DIRI, we had to develop a large and diverse network of centers to enroll high quality research subjects. The international network of top nephrology researchers we have assembled, will be vital to securing adequate numbers of diverse, well characterized DIRI cases for the DIRECT Study."

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 (www.saeconsortium.org). 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.

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