Contact: Arthur L. Holden
Chairman and CEO,
International Serious Adverse Event Consortium
8770 W. Bryn Mawr Avenue, Suite 1300
Chicago, IL 60631-3515
Phone: 773-867-8595

THE INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM ANNOUNCES PRED4 STUDY TO RESEARCH THE ROLE GENETICS PLAYS IN DRUG INDUCED SERIOUS EVENTS ASSOCIATED WITH INFLAMMATORY BOWEL DISEASE TREATMENT

The PRED Study focuses on research the role of genetics in major treatments associated with Inflammatory Bowel Disease therapy.

Chicago, IL (August 8, 2013) – The International Serious Adverse Events Consortium (iSAEC) announced today an important pharmaco-genetics research effort, the PRED4 Study, to research the role genetics plays in rare complications associated with Inflammatory Bowel Disease (IBD). The Predicting Serious Drug Side Effects in Gastroenterology (PRED) study is being executed in conjunction with Royal Devon & Exeter Hospital (UK) (http://www.rdehospital.nhs.uk/), and it also serves as the coordinating center for this international research effort. 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 PRED Study represents the iSAEC's first effort to comprehensively research the genetics of drug induced serious adverse reactions (SAEs) associated with IBD therapy. Specifically, the PRED Study is focused on five major initial IBD phenotypes, including:

- 5ASA induced nephrotoxicity,
- Thiopurine induced pancreatitis,
- Thiopurine induced leucopenia,
- Proton Pump Inhibitor induced interstitial nephritis, and
- Demyelination complicating anti-TNF therapy.

The PRED Study is being led by Tariq Ahmad, MD, PhD, and Consultant Gastroenterologist at the Royal Devon & Exeter Hospital in England. The PRED Study has, to date, recruited approximately 900 IBD patients, over the past 18 months, through a collaborative network of over 50 leading clinical research/gastroenterology centers from around the world. Some of these cases have already been characterized and are being analyzed at the Broad Institute (http://www.broadinstitute.org/). The Broad Institute has been a vital contributor to research into the genetics underlying IBD disease.

“There are a series of rare, but serious adverse responses associated with the treatment of IBDs such Crohn's disease and Ulcerative colitis.” said Arthur L. Holden, Chairman and CEO of the iSAEC. “To better understand the full genetic effects contributing to IBD SAEs, we are partnering with Royal Devon & Exeter Hospital and the International IBD Consortium to enroll high quality IBD research subjects. We expect to see similar patterns of genetic contribution, as we have seen in our ground breaking research into the genetics of drug-induced liver and skin injury."

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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