iSAE Consortium Ltd.

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CONSORTIUM OF FINNISH UNIVERSITIES TO PARTNER WITH THE INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM TO RESEARCH THE GENETICS OF DRUG INDUCED LIVER INJURY AND SKIN INJURY USING ELECTRONIC HEALTH RECORDS

Helsinki University Hospital to lead collaborative effort to study the role of genetic variation in drug induced liver and skin injury in Finnish subjects

Chicago (November 17, 2011) – The International Serious Adverse Events Consortium (iSAEC) announced today it will collaborate with Helsinki University and a network of Finnish hospitals to research the genetics of drug induced liver and skin injury. The iSAEC is a novel, non-profit international research consortium, formed by the global pharmaceutical industry and the Wellcome Trust, to better understand the role genetics plays in drug safety. Helsinki University is one of Finland's top research universities and has an impressive history of pioneering genetic and other biomedical research. The collaboration will be directed by Tarja Laitinen, M.D., Ph.D. (Head of the Department of Pulmonary Medicine) at Helsinki University Hospital.

The SAEC's International Drug Induced Liver Injury Consortium (IDILIC) is actively recruiting patients with drug induced serious liver, skin and kidney injury reactions, through a collaborative network of leading research centers around the world. Through this collaboration, the iSAEC will support the use of Finland's well established electronic medical record system to identify and enroll subjects who have experienced the target adverse reactions.

“Our genetic research to date points to a strong role of the immune system in these reactions.” said Arthur L. Holden, Chairman of the SAEC. “To better understand the full genetic effects contributing to these diseases, we need to develop larger and more diverse collections of subjects, in conjunction with international researchers who share our strong interest and have experience with these adverse drug reactions. We are thrilled Helsinki University and Dr. Tarja Laitinen share our commitment to our large scale international research collaboration into the genetics of these responses.”

Founded in the fall of 2007, the SAEC is a private, global partnership of leading pharmaceutical companies, the U.S. Food and Drug Administration and academic institutions from around the world to identify and confirm genetic markers that may help predict which patients are at risk for drug-related serious adverse events. Through identifying and ultimately validating genetic markers associated with SAEs, the Consortium hopes to reduce the patient and economic costs caused by drug-related SAEs. The SAEC also hopes to improve the flow of safe and effective medical therapies by better addressing idiosyncratic safety risks of new drugs before they reach the market. It provides to qualified researchers, free access to its study data and results.

About the International SAEC
The International Serious Adverse Event Consortium (SAEC, www.saeconsortium.org) is a 501(c) 3 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.

SAEC members include representatives from the pharmaceutical industries, the scientific community, and the Wellcome Trust.

- Pharmaceutical industry partners are involved in all aspects of the Consortium launch, providing ongoing consultation on the development and structure of the Consortium's scientific model, contributing cohort data, and underwriting costs of the SAEC's studies.

- SAEC members include Abbott, Amgen, Astra-Zeneca, Daiichi Sankyo, GlaxoSmithKline, Merck, Novartis, Pfizer, Takeda, and the Wellcome Trust.

- The FDA provides consultation on the direction of the SAEC, the design and conduct of SAEC studies, and support of research data release.

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