



Contact: Arthur Holden
Chairman, SAE Consortium, Ltd.

8770 W. Bryn Mawr Ave., Suite 1300
Chicago, Illinois
Phone: 1-773-867-8595

**INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM (SAEC)
ANNOUNCES ITS FOURTH DATA RELEASE FROM ITS GLOBAL RESEARCH
COLLABORATION TO IDENTIFY GENETIC MARKERS RELATED TO DRUG
INDUCED SERIOUS ADVERSE EVENTS**

*Nonprofit consortium unites industry, academia and government in the study of the
genetics of drug safety*

Chicago (September 30, 2010) – The International Serious Adverse Events Consortium (SAEC) announced today its fourth data release from its research efforts designed to discover genetic markers that may predict individuals at risk for serious drug induced liver injury (DILI) and cardiac arrhythmia. The SAEC is a nonprofit research corporation, launched in the fall of 2007, now in its second phase of research, comprised and funded by leading pharmaceutical companies and the Wellcome Trust. The U.S. Food and Drug Administration (FDA) also contributes to the scientific and strategic direction of this novel research effort. The collection and initial characterization of the DILI cases supporting these results was performed by member pharmaceutical companies. The collection and initial characterization of the cardiac arrhythmia cases supporting these results was performed by the Drug-Induced Arrhythmia Risk Evaluation (DARE) Network, in conjunction with St. George's University of London.

Patients respond differently to medicines, and all medicines can have adverse effects in some people. The SAEC's work is based on the hypothesis that many of these differences may have a genetic basis. Its research studies are exploring the impact genetics can have on how individuals respond to medicines. There are a large number of drugs that can cause liver injury or skin rashes in a small subset of patients. Although the exact mechanisms behind such rare and unpredictable serious adverse reactions are unknown, research suggests a genetic contribution.

The fourth released research data relates to DILI (77 cases) and cardiac arrhythmia (103 cases), and complement the already released SAE case datasets from the SAEC's December, 2008, May, 2009 and December 2009 data releases. The data relating to the 77 DILI and 103 cardiac arrhythmia cases are being released with a publication embargo of **July 30, 2011**. This will allow ample time for completion of two planned papers by the SAEC on the genetics of DILI and cardiac arrhythmia.

These data can be accessed via the SAEC's (www.saeconsortium.org) website. Qualified researchers, who enter into a data use agreement, can obtain free access to these data for exclusive use in biomedical research.

SAEC Membership and Collaborators

The SAEC'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 SAE research/operations. The SAEC's 10 Phase 2 funding members include: Abbott, Amgen, AstraZeneca, Daiichi Sankyo, GlaxoSmithKline, Merck, Novartis, Pfizer, Takeda and the Wellcome Trust.
- SAEC 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.
- The FDA is providing consultation on the conduct of SAEC studies and data release.

#

About the SAEC

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 partnership currently dedicated to studying SAE genomics.