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 THIRD DATA RELEASE RELATING TO 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 (December 30, 2009) – The International Serious Adverse Events Consortium (SAEC) announced today its third 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 Serious Skin Rashes (SSR). The SAEC is a nonprofit research corporation, launched in the fall of 2007, comprised and funded by 10 leading pharmaceutical companies and the Wellcome Trust. The U.S. Food and Drug Administration (FDA) also contribute 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 the UK-based DILIGEN network, the Spanish DILI network (Malaga University), and EUDRAGENE network (London School of Public Health and Tropical Medicine). The collection and initial characterization of the SSR cases supporting these results was performed by GSK and the Italian SSR Network (University of Florence).

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 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 livery 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 released research data relating to DILI (367 cases) and SSR (19 cases), complement the already released DILI and SSR case data from the SAEC's December, 2008 and May, 2009 data releases. All data relating to SSR are being released with no publication embargo dating. The data relating to the 367 DILI cases are being released with a publication embargo of **September 30, 2010**. This will allow ample time for completion of two planned papers by the SAEC on the genetics of DILI.

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 1 funding members include: Abbott, Daiichi Sankyo, F. Hoffmann-La Roche, GlaxoSmithKline, Johnson & Johnson Pharmaceutical Research & Development, Novartis, Pfizer, Sanofi-Aventis Takeda, and Wyeth.

- The Wellcome Trust [London] provides funding, research data and strategic direction to the SAEC.

- Collaborative research partners are helping to collect and analyze data from the SAEC studies. Partners include DILIGEN (Newcastle University, University of Liverpool and Queen's Medical Centre, Nottingham), EUDRAGENE (a European academic consortium conducting research on drug-related liver toxicity), University of Dundee and Illumina, Inc. Columbia University serves as the Consortium's data analysis and coordinating center.

- The FDA is providing consultation on the conduct of SAEC studies and data release.

# # #

About the SAEC
The Serious Adverse Event Consortium (SAEC) 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.

***501(c)** is a provision of the United States Internal Revenue Code (26 U.S.C. § 501(c)), listing twenty-seven types of non-profit organizations exempt from some Federal income taxes.