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TWO ACADEMIC COLLABORATORS JOIN INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM (SAEC) TO HELP FURTHER DRUG INDUCED LIVER INJURY RESEARCH EFFORT

Two leading academic collaborators partner with innovative research consortium

Chicago (June 25, 2008) – The International Serious Adverse Events Consortium (SAEC) announced today that two new leading academic centers will collaborate with this novel, international research Consortium, which is working to identify genetic markers that may help predict which individuals are at risk for a range of serious drug-related adverse events (SAEs). These new research collaborators include the University of Malaga [Malaga, Spain] and the University of Dundee [Dundee, Scotland]. The parties' collaboration will center on the recruitment, enrollment, and whole genome genotyping of patients with drug induced liver injury (DILI). Additional DILI patients will be recruited into the Consortium's research effort, using both traditional academic referral networks and novel electronic medical information systems.

Founded in the fall of 2007, the SAEC is a global partnership between 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 significant 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.

One of the Consortium's initial studies is focused on identifying the genetic markers associated with drug-related liver toxicity (the leading cause of acute liver failure[i]), which is associated with over 200 different medicines. In these studies, the SAEC is currently collecting DNA samples and clinical data from subjects who experienced drug-related liver toxicity via collaborations with two leading UK based drug safety research networks [i.e Eudragene and the Diligen Network]. The SAEC will compare the genetic and clinical data from these "cases" to a healthy control group, with the goal to identify genetic mutations that are associated with the SAE. Through this initial research, the Consortium hopes to provide a foundation for the next generation of studies that will validate the role of these genetic variations in the development of drug-related SAEs. The SAEC has established its information technology (IT) infrastructure, at its data analysis and coordinating center at Columbia University, to provide the research community with free and unencumbered access to study data. Results generated from these initial genetic association studies will be available to all qualified researchers for future study and validation.

"With these additional collaborations with Malaga and Dundee, we are well on our way to developing the world's pre-eminent international DILI molecular research consortium," said Arthur L. Holden, Chairman of the SAEC. "By combining European DILI research efforts through the SAEC, we will successfully aggregate the required number of patient events required to research this important public health need. Initial data analysis results on our DILI cohort point to the fact significant genetic factors may be at work in this disease."

About the International SAEC
The International 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.

SAEC members include representatives from the pharmaceutical and diagnostics industries, scientific community, and government.

- Pharmaceutical industry partners have been closely 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 SAEC studies. SAEC members include: Abbott, GlaxoSmithKline, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Pfizer, Roche, sanofi-aventis and Wyeth. Joining them now are Daiichi Sankyo, Novartis and Takeda.

- Clinical/Research partners are helping to collect and analyze data from the SAEC studies. Partners include Newcastle University/DILIGEN, EUDRAGENE (a European academic Consortium conducting research on drug-related liver toxicity) and Expression Analysis, Inc. Columbia University is hosting the Consortium's data analysis and coordinating center.

- Medical research charities are providing their guidance and expertise on the scientific process along with financial support. The latest to join is The Wellcome Trust.

- The FDA is providing consultation on the direction of the SAEC, and the design and conduct of SAEC studies. The SAEC will also consult the EMEA (the European Agency for the Evaluation of Medicinal Products) and other international regulatory bodies for guidance on its efforts.

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[i] "Drug-Induced Liver Toxicity." U.S. Food & Drug Administration. 9 Mar. 2007. 16 July 2007 <http://www.fda.gov/cder/livertox/>.