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**ACADEMIC COLLABORATOR PARTNERS WITH THE INTERNATIONAL SERIOUS
ADVERSE EVENTS CONSORTIUM (SAEC) TO CONDUCT GENOMIC RESEARCH ON
DRUG INDUCED CARDIAC ARRHYTHMIA**

Leading UK academic collaborator to partner with innovative research consortium

Chicago (April 8, 2009) – The International Serious Adverse Events Consortium (SAEC) announced today that the St. George's University of London The Drug Safety Research Unit (DSRU) and the Drug-Induced Arrhythmia Risk Evaluation (DARE) Network will collaborate with this novel, international research consortium, which is working to identify genetic markers that may predict which individuals are at risk for drug-induced torsades de pointes. The collaboration was facilitated by London Genetics Limited.

Drug-induced torsades de pointes (TdP) is a serious ventricular arrhythmia and is associated with a prolongation of the QT interval. The risk of TdP varies across patient characteristics and drugs classes. The collaboration will focus initially on conducting a genome-wide association study (GWAS) to identify significant genetic markers associated with TdP in Caucasian subjects. 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.

“Our research efforts, since our launch in late 2007, have focused on the genetics of drug induced liver injury and serious skin rashes. We are very pleased to be able to expand our research breadth into the genetics of drug induced arrhythmias with St. George's University of London and the DARE Network.” said Arthur L. Holden, Chairman of the SAEC. “Although the genetics of congenital long QT syndrome (CLQTS) is being explored by numerous research teams around the world, the drug induced forms of this disease still require rigorous genetic studies across ethnicities and drug classes.”

St George's participation will be lead by Dr Elijah R Behr, Senior Lecturer in Cardiological Sciences, and Professor of Cardiology, John Camm. Dr Behr said “This collaboration with the SAEC offers exciting opportunities for the DARE study to continue its work. The genetic studies involved will permit the identification of genetic risks that predispose individuals to this lethal side-effect of certain medications and allow the development of new preventative strategies.”

About The DARE Study

The DARE study is a collaboration between St George's and the Drug Safety Research Unit in Southampton, funded by the British Heart Foundation, to determine whether there is a genetic reason for prescription drug-induced arrhythmia. The five-year study analysed the genetic

make-up of patients who developed the potentially fatal condition after taking certain medications, to identify a pattern.

About St George's University of London [www.sgul.ac.uk],

St George's, University of London is a college of the University of London dedicated to the study of medicine and healthcare sciences. SGUL is co-located with one of the UK's busiest hospitals, St George's Healthcare NHS Trust. This provides a wealth of expertise in clinical and biomedical research and has resulted in leading edge research and clinical trial activity.

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.

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.

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, Daiichi Sankyo, GlaxoSmithKline, Johnson & Johnson, Novartis, Pfizer, Roche, Sanofi-Aventis, Takeda and Wyeth.
- Clinical/Research partners are helping to collect and analyze data from the SAEC studies. Partners to date include Newcastle University/DILIGEN, EUDRAGENE (a European academic Consortium conducting research on drug-related liver toxicity) Malaga University, Dundee University 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.

Notes for Editors

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