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FOUR LEADING COMPANIES JOIN INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM (SAEC) TO HELP FURTHER GLOBAL RESEARCH COLLABORATION

Three global pharmaceutical companies and the world's largest medical research charity join innovative research consortium

Chicago (May 29, 2008) – The International Serious Adverse Events Consortium (SAEC) announced today that four new members have joined this novel 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 members include pharmaceutical companies Takeda, Novartis and Daiichi Sankyo and the world's largest medical research charity, The Wellcome Trust.

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.

"In the development and study of therapies, we are always concerned about the potential for patients to experience serious adverse events," said Dr. Leonardo Sahelijo, Director of Pharmacogenomics at Takeda Global Research and Development Center. "By combining our efforts through the SAEC, we can work to improve our own individual processes, while achieving the large number of patient events that are required to address this important research and public health need."

The Consortium's initial studies focus on identifying the genetic markers associated with drug-related liver toxicity (the leading cause of acute liver failure[i]) and Stevens Johnson Syndrome (SJS), a rare but serious skin condition which is associated with over 200 different medicines. In these studies, the SAEC is collecting DNA samples and clinical data from subjects who experienced drug-related liver toxicity or SJS. 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 is also creating the 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 association studies will be available to all qualified researchers for future study and validation.

"These new members will help to further our objective of building a solid foundation of research to study and ultimately try to determine how and why people have different responses to different medicines," says SAEC chairman and CEO Arthur Holden. "The involvement of companies from around the world, like our new members, is a critically important development

to help us meet our research goals. Furthermore, the Wellcome Trust has long been a leader in the development of genomic research tools and databases, so we are thrilled to have them on board to help us lead the development of the SAEC. ”

The new pharmaceutical partners will provide scientific leadership, funding and possibly “cases” to enhance the Consortium’s research endeavors. Additionally, The Wellcome Trust will contribute financial support, as well as guidance and expertise in the design and execution of current and future studies. The Wellcome Trust’s membership will also allow the SAEC to learn from and leverage capabilities developed as part of its “Case-Control Consortium.”

“The work of the SAEC promises to be important in moving forward the study of the molecular basis of drug induced serious adverse events, and in providing leadership in this area” said Alan Schafer, Ph.D., Head of Molecular and Physiological Sciences at the Wellcome Trust. “We are pleased to be a part of this international research Consortium and to contribute to a new era in scientific study.”

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/>.