SAE Consortium Ltd.

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INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM (SAEC) LAUNCHES GLOBAL RESEARCH COLLABORATION TO IDENTIFY GENETIC MARKERS RELATED TO ADVERSE DRUG REACTIONS

Newly formed nonprofit corporation unites industry, academia and government in first large-scale study of genetics and drug safety

Chicago (September 27, 2007) – The International Serious Adverse Events Consortium (SAEC) announced today its formation and plans to launch two initial research programs designed to identify genetic markers that may help predict which individuals are at risk for serious drug-related adverse events (SAEs). The two studies will address drug-related liver toxicity and a rare but serious drug-related skin condition called Stevens-Johnson Syndrome (SJS). The SAEC is a nonprofit corporation comprised of leading pharmaceutical companies, and academic institutions with scientific and strategic input from the U.S. Food and Drug Administration (FDA).

Patients respond differently to medicines and all medicines can have side effects in some people. The SAEC's work is based on the hypothesis that these differences have a genetic basis, and its research studies will examine the impact genes can have on how individuals respond to medicines.

The results from SAEC research studies will be made available to the research community for further study. These studies will eventually arm drug developers, biomedical researchers and pharmaceutical companies with genetic markers that help them address safety issues of new drugs in development. SAEC research results may also provide physicians with more information on the balance between the benefits and risks of medicines if an individual has a specific genetic variation that is linked with an increased risk of adverse events.

"Developing new scientific approaches to detect, understand, predict and prevent serious drug-related adverse events is at the heart of FDA's ambitious plans to strengthen our drug safety system. We are encouraged that this new consortium will play an important role in enhancing drug safety by accelerating and advancing our understanding of genetic variants associated with these adverse events," said Janet Woodcock, M.D., FDA's deputy commissioner and chief medical officer. "Given the considerable time, size and cost of conducting safety studies, a coordinated, strategic partnership between industry, academia, and government can more rapidly advance this critical science."

An Innovative Research Model

To complete the analyses, the SAEC will use an innovative research model that combines the resources of the participating pharmaceutical companies and academic research partners and capitalizes on knowledge gained through the mapping of the human genome. Pharmaceutical companies have been gathering data on drug-related liver toxicity and SJS in their own studies for many years, but because the rates of these

events are relatively low, the data from each company may be insufficient to make predictions about risk.

"The traditional research model only provides one piece of the puzzle in understanding the genetic variations that could lead to an increased risk of an adverse event," says SAEC chairman and CEO Arthur Holden. "Because of the number of patients needed to tie a genetic variant to an SAE, and the resulting cost of doing these studies, no one company, research center, or agency can efficiently conduct this research on its own. The most efficient way to study drug-related SAEs is to create a global, publicly available 'knowledge base' that will help identify the genetic variations that may predict SAEs."

The SAEC plans to collect already available SAE data from the participating pharmaceutical companies and academic institutions in streamlined databases. These well-characterized databases of DNA from individuals who have experienced drug-related liver toxicity and SJS will then be compared with control cases to identify genetic variants that may be associated with these SAEs. To identify the genetic variations linked with the SAEs, researchers will use data from The SNP Consortium and Hap Map Project, which mapped genetic variants (single nucleotide polymorphisms, or SNPs) in conjunction with the Human Genome Project. The identification of such genetic variations is believed to be important in identifying patients for whom a medicine will have the greatest likelihood of providing medical benefits, with the lowest risk of an accompanying serious adverse event.

SAEC Research Goals and Longer-Term Plans

The SAEC's initial studies, focused on identifying the genetic markers associated with drug-related liver toxicity (the leading cause of acute liver failure[i]) and SJS, will 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. All research results will be available publicly within 12 months of the completion of the study group's genotyping. The SAEC will create the information technology (IT) infrastructure to provide the research community with free and unencumbered access to study data. Results obtained in initial studies will be reevaluated by researchers who can then determine their validity as predictive markers.

In addition to supporting original research of drug-related SAEs, the SAEC will:

- Establish open-use research practices and standards
- Encourage greater efficiency by pooling talent and resources under a common leadership with public safety-driven goals
- Enhance the public's understanding of how the industry, academia and government are partnering to address drug-related adverse events

The SAEC is also exploring partnerships with other private and government institutions to continue their research. If their initial studies are successful, the SAEC hopes to examine other major drug-related adverse events to determine their underlying genetic causes.

SAEC Membership

SAEC members include representatives from the pharmaceutical industry, 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. Founding SAEC members include: Abbott,

GlaxoSmithKline, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Pfizer, Roche, sanofi-aventis and Wyeth.

- 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 Illumina, Inc. Columbia University will host the Consortium's data analysis and coordinating center.

- The FDA is providing consultation on 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 national regulatory bodies for guidance on its efforts.

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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.

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