SAE Consortium Ltd.

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RESEARCH PARTNERSHIP WILL STUDY HOW ELECTRONIC MEDICAL RECORDS CAN ADDRESS GENETICS OF DRUG SAFETY

Nation's premier health maintenance research group to collaborate with innovative international genomics research consortium

Chicago (October 21, 2009) – The International Serious Adverse Events Consortium (SAEC) announced today it will collaborate with the HMO Research Network (HMORN) to improve the safe use of drugs by exploring why the genetic makeup of some individuals makes them more likely to experience serious drug-related adverse events (SAEs). The SAEC is a novel, non-profit international research consortium. The HMORN is the nation's premier resource for population-based health care outcomes research.

The collaboration will diversify the SAEC methods for developing SAE research cohorts, which is essential to furthering research goals of the organization. It will determine the feasibility of using the HMORN's centralized clinical data warehouse to research the genetics of drug-induced serious adverse events. This warehouse includes data relating to inpatient admissions and emergency room and outpatient visits representing 14 million unique patients. The research collaboration will initially focus on three drug-induced SAEs: hepatotoxicity, serious skin rashes, and extreme weight gain in users of atypical antipsychotic medications.

Initially, the collaboration will involve six members of the HMORN: Geisinger Center for Health Research, Group Health Research Institute, HealthPartners Research Foundation, Kaiser Permanente Center for Health Research-Southeast, Kaiser Permanente Center for Health Research-Hawaii and Marshfield Clinic Research Foundation. Each HMO will use detailed clinical profiles to search for potential subjects to enroll into current and future SAE research projects. Accuracy and completeness of the data will be assessed, as well as methods to ensure that data are robust. The first phase of this collaboration is expected to take 12 months.

The collaborators hope to derive "cases" from electronic medical records (EMRs) and eventually compare their genetic and clinical data with those of healthy control groups. The goal is 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. **In this phase of the collaboration, no individual health records or health information will be released by any of the participating institutions in connection with this research.** To date, the SAEC has already made significant genetic discoveries in support of its mission. The HMORN-SAEC collaboration is expected to facilitate the discovery of additional genetic findings.

"Our efforts to date on drug-induced liver injury and serious skin rashes have leveraged traditional academic networks recruiting research subjects across a limited number of hospitals," said Arthur L. Holden, Chairman of the SAEC. "By working with these leading HMOs, all of which have sophisticated electronic medical records and outstanding clinical research capabilities, we hope to open up a new, more scalable research channel to enroll subjects into this vital research. Our goal is to increase the breadth and diversity of patients participating and

to provide our clinical research collaborators with larger, more developed research cohorts more efficiently and effectively."

"Many adverse drug reactions are likely related in some way to genetic differences among patients," said Robert Davis, MD, director of the Kaiser Permanente Center for Health Research-Southeast and a member of the HMO Research Network. "If we can identify these differences before prescribing medications, we can help promote the safest use of medications. With our large and ethnically diverse populations, and the wide range of medications used, the HMORN is an ideal partner for this type of collaboration."

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

The SAEC has established its information technology (IT) infrastructure at its data analysis and coordinating center at Columbia University. It will 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.

About the International SAEC
The International Serious Adverse Event Consortium (SAEC, www.saeconsortium.org) 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 industries, the scientific community, and the Wellcome Trust.

- 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 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.

- The FDA is providing consultation on the direction of the SAEC and the design and conduct of SAEC studies.

About the HMORN

The HMO Research Network (www.hmoresearchnetwork.org) is a consortium of 16 geographically diverse health plans in the United States and Israel with integrated research divisions committed to public-domain research that advances population health through its work with 14 million health plan members. Collectively, the HMORN represents several hundred doctoral-level investigators, clinical researchers, and associated research personnel.

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