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iSAEC AND HMORN COLLABORATE TO USE ELECTRONIC MEDICAL RECORDS TO RESEARCH GENETICS OF DRUG-INDUCED SAEs

The nation's premier health maintenance research group to further its partnership with innovative international genomics research consortium

Chicago (February 02, 2011) – The International Serious Adverse Events Consortium (iSAEC) announced today a new collaboration with the HMO Research Network (HMORN) to enroll subjects in research to identify genetic markers that may help predict risk associated with a range of serious drug-related adverse events (SAEs). The collaboration will diversify the iSAEC methods for developing SAE research cohorts, an essential component of the Consortium's Stage II research. Through the collaboration, the iSAEC will use the HMORN's centralized clinical data warehouses, across nine HMOs, to build research cohorts associated with the genetics of three drug-induced SAEs: hepatoxicity; serious skin rashes; and extreme weight gain in users of atypical antipsychotic medications.

The nine HMORN members participating in this collaboration are: *HealthPartners Research Foundation; Kaiser Permanente Georgia; Kaiser Permanente Hawaii; Marshfield Clinic Research Foundation; Group Health Collaborative and Geisinger Center for Health Studies; Henry Ford Health Care; Kaiser Permanente Southern California; Harvard Pilgrim Health Plan; and Kaiser Permanente Colorado*. Each member will use detailed clinical profiles to search for potential subjects to enroll into these SAE research projects using their electronic medical record (EMR) databases. This second phase of this on-going collaboration is expected to take twenty four months.

"Our efforts to date on drug induced immunologic SAEs have mainly leveraged traditional academic networks, recruiting research subjects across a limited number of hospitals," said Arthur L. Holden, Chairman of the iSAEC. "By working with these nine leading HMOs, all of whom have sophisticated EMRs 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 increase the breadth and diversity of patients participating and to provide our clinical research collaborators with larger, more developed research cohorts in a more efficient and effective manner."

The collaborators plan to compare the genetic and clinical data from EMR derived "cases" to healthy control groups, with the goal of identifying genetic mutations that are associated with the specific SAE. To date, the iSAEC has already made significant genetic discoveries in support of its mission to better understand the role of genetics in drug-induced SAEs. The HMORN-iSAEC collaboration will facilitate the discovery and validation of these and additional genetic findings.

"Many adverse drug reactions are probably a result of 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. "Through our research with the iSAEC, we hope to identify these differences and screen patients before they are treated, thereby reducing morbidity and mortality associated with drug therapies. Because of our large population, ethnic

diversity, and the wide range of medications prescribed, the HMORN is an ideal partner for this collaboration."

Founded in the fall of 2007, the iSAEC is a private, global partnership of leading pharmaceutical companies, the U.S. Food and Drug Administration and academic research institutions from around the world, working to identify and confirm genetic markers that may help predict which patients are at risk for drug-induced SAEs. 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 iSAEC 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 iSAEC has its information technology (IT) infrastructure at its data analysis and coordinating center at Columbia University (New York). It provides qualified researchers with free and unencumbered access to its research data, for further study and validation.

About the International SAEC
The International Serious Adverse Event Consortium (iSAEC, 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. The iSAEC partners are providing financial support, in-kind donations, and participation in data collection to the Stage II research.

The iSAEC is the only privately-funded industrial consortium dedicated to studying SAE genomics. iSAEC's members include Abbott, Amgen, Astra-Zeneca, Cerner, Daiichi Sankyo, GlaxoSmithKline, Merck, Novartis, Pfizer, Takeda, and the Wellcome Trust. The FDA provides consultation on the direction of the SAEC and support of research data release.

About the HMORN
The HMO Research Network (www.hmoresearchnetwork.org) is a consortium of 16 geographically diverse health plans in the US with integrated research divisions committed to public domain research that advances population health through its work with nearly 14 million health plan members. Collectively, the HMORN represents several hundred doctoral-level investigators, clinical researchers, and associated research personnel. The 16 HMORN member sites have a strong track record of research. The vision of this productive enterprise is to serve as the research partner of choice for those seeking to shape public health and health care delivery.

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