SAE Consortium Ltd.

Contact: Arthur Holden
Chairman and CEO, SAE Consortium, Ltd.
8770 W. Bryn Mawr Avenue, Suite 1300
Chicago, Illinois
Phone: 1-773-867-8595

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THE INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM ANNOUNCES PUBLICATION OF WHOLE GENOME STUDY OF DRUG INDUCED SERIOUS SKIN RASH

Important initial whole genome genotyping research results from innovative international genomics research consortium

Chicago (January 30, 2011) – The International Serious Adverse Events Consortium (iSAEC) announced the publication of "Genome-wide Association Study of Serious Blistering Skin Rash Caused by Drugs" in the Pharmacogenomics Journal (January 2011). Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are rare but severe, potentially life threatening adverse drug reactions characterized by skin blistering. Previous studies had identified drug-specific and population-specific genetic risk factors associated with SJS/TEN. This study represents the first genome-wide association study of SJS/TEN induced by a wide variety of drugs. Its aim was to identify common genetic risk factors with potential utility in predicting SJS/TEN risk. Although no genome-wide significant associations with SNPs or copy number variants (CNVs) were observed in this initial study, there were several genomic regions identified that could play a role in predisposing patients to drug-induced SJS/TEN. The study, although an important first step, clarified the need for larger drug and ethnicity specific cohorts to better understand the genetics of drug-induced serious skin rash.

This research was underwritten by the iSAEC and conducted by its data analysis and coordinating center at Columbia University. Contributions of SJS/TEN cases were made by GlaxoSmithKline, the Wellcome Trust, and European investigators.

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-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 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. It provides the research community with free and unencumbered access to study data. Results generated from its genetic association studies are available to all qualified researchers for future study and validation.

“This effort to investigate the genetics of drug-induced serious skin rash on a genome-wide scale represents an important step,” said Matt Nelson, PhD (GlaxoSmithKline), co-chairman of the iSAEC's scientific management committee. “We have gained greater insight into the genomic influence on this serious adverse reaction and demonstrated that there are no common genetic variants imparting a large risk across drugs. We are now expanding the depth and diversity of this clinical cohort through the iSAEC-supported International Hypersensitivity Consortium (ITCH) to better assess genetic risks for specific drugs. This work, in conjunction with advancements into sequencing entire genomes of patients, should provide a better understanding of the genetics associated with this serious condition.”

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. 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.

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