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INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM (SAEC) ANNOUNCES ITS FOURTH DATA RELEASE FROM ITS GLOBAL RESEARCH COLLABORATION TO IDENTIFY GENETIC MARKERS RELATED TO DRUG INDUCED SERIOUS ADVERSE EVENTS

Nonprofit consortium unites industry, academia and government in the study of the genetics of drug safety

Chicago (November 2, 2011) – The International Serious Adverse Events Consortium (SAEC) announced today its fifth data release from its research efforts designed to discover genetic markers that may predict individuals at risk for Agranulocytosis induced by Clozapine (CIA). The SAEC is a nonprofit research corporation, launched in the fall of 2007. The SAEC is now in its second phase of research which is funded and overseen by leading pharmaceutical companies and the Wellcome Trust. The U.S. Food and Drug Administration (FDA) also contributes to the scientific and strategic direction of this novel research effort. The collection and sequencing of the CIA cases supporting this study was performed by member companies and the Duke University Center for Human Variation, respectively.

Patients respond differently to medicines, and all medicines can have adverse effects in some people. The SAEC's work is based on the hypothesis that many of these differences may have a genetic basis. Its research studies are exploring the impact genetics can have on how individuals respond to medicines. Although the exact mechanisms behind such rare and unpredictable serious adverse reactions are unknown, research suggests a genetic contribution.

The fifth released research data relates to 33 CIA cases who's exomes were fully sequenced. The data release includes related clinical data, genetic variant calls, and Illumina 601 k SNP data. These data can be accessed via the SAEC's (www.saeconsortium.org) website. Qualified researchers, who enter into a data use agreement, can obtain free access to these data for exclusive use in biomedical research.

SAEC Membership and Collaborators

The SAEC's participants include representatives from the pharmaceutical industry, the scientific community, and government.

- Pharmaceutical industry members are closely involved in all aspects of the Consortium's research, providing ongoing consultation on the development and structure of the Consortium's scientific models, and contributing cohort data and underwriting costs of SAE research/operations. The SAEC's 10 Phase 2 funding members include: Abbott, Amgen, AstraZeneca, Daiichi Sankyo, GlaxoSmithKline, Merck, Novartis, Pfizer, Takeda and the Wellcome Trust.
- SAEC provides researchers with open access to its data through a controlled-access database. Twelve months after genotyping studies are complete, data is

released without any patent or intellectual property constraints, allowing for further use and study by interested researchers.

- The FDA is providing consultation on the conduct of SAEC studies and data release.

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About the SAEC

The International Serious Adverse Event Consortium (iSAEC) is a 501(c) 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 partnership currently dedicated to studying SAE genomics. The iSAEC is lead by Arthur L. Holden, who serves as its Chairman and CEO.