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THE INTERNATIONAL SERIOUS ADVERSE EVENT CONSORTIUM (iSAEC) ANNOUNCES COMPLETION OF CLINICAL ENROLLMENT INTO ITS DRUG INDUCED LIVER INJURY (DILI) AND HYPERSENSITIVITY/SKIN RASH (ITCH) GENOMICS COHORTS

After three years of clinical recruitment the iSAEC announces the completion of its Phase 1 clinical recruitment to enable its vital safety pharmaco-genetics research.

Chicago, IL (August 07, 2013) – The International Serious Adverse Events Consortium (iSAEC) announced today the completion of the first phase of its international clinical recruitment, in support of its research into genetic contributors to drug induced liver injury (DILI) and hypersensitivity/skin injury (DISI). The iSAEC is a novel, non-profit international research consortium, funded by the global pharmaceutical industry and the Wellcome Trust, to better understand the role genetics plays in drug safety and response.

The International Drug Induced Liver Injury Network (iDILIC), launched in 2010 under the direction of Professor Ann Daly (Newcastle University, England), is the iSAEC's major effort to comprehensively research the genetics of DILI, through a strategy that focuses on key causal drugs and diverse population groups that have experienced DILI. The iDILIC Network has successfully enrolled over 1,300 DILI patients, through an international collaborative network. These cases, although predominantly of European descent, also contain significant numbers of cases of Indian and Asian descent. The major drugs associated with the iDILIC cohort include amoxicillin-clavulanate, other major antibiotics, statins, NSAIDs, anti-TB drugs, and anti-TNF drugs. These cases are currently being characterized at the Broad Institute (http://www.broadinstitute.org/). They will be combined with select DILI cases from the DILIN Study (https://dilin.dcri.duke.edu), and will be jointly analyzed by the two research groups.

The International Hypersensitivity Network (ITCH), launched in 2010 under the direction of Professor Munir Pirmohamed (Liverpool University, England) is the iSAEC's major effort to comprehensively research the genetics of DISI, through a strategy that focuses on key causal drugs and diverse population groups that have experienced DISI. The ITCH Network has successfully enrolled over 1,330 DISI patients, through an international collaborative network. These cases, although predominantly of European descent, also contain significant numbers patients of African descent. The major drugs associated with the ITCH cohort include amoxicillin-clavulanate, other beta-lactam antibiotics, carbamazepine, and anti-AIDS drugs. These cases are currently being characterized at the Broad Institute (http://www.broadinstitute.org/) and will be analyzed at the iSAEC's Data Analysis and Coordinating Center at Columbia University.

"Our genetic research points to a strong role of the immune system in contributing to these rare, but serious adverse responses. To better understand the full genetic effects contributing to DILI and DISI, iSAEC had to develop a large and diverse network of research centers to enroll high quality research subjects, said Arthur L. Holden, Chairman and CEO of the iSAEC. We couldn't be more pleased with the number and diversity of the research subjects recruited."

About the iSAEC (http://www.saeconsortium.org)

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 international partnership dedicated to studying the genomics of drug induced serious adverse events.

iSAEC Membership and Collaborators
The iSAEC'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 the iSAEC's research/operations. The iSAEC's Phase 2 funding members include: Abbott, Amgen, AstraZeneca, Daiichi Sankyo, GlaxoSmithKline, Merck, Novartis, Pfizer, Takeda and the Wellcome Trust.
- iSAEC provides researchers with open access to its data through a controlled-access database (www.saeconsortium.org). 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.

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