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INTERNATIONAL SERIOUS ADVERSE EVENTS CONSORTIUM (iSAEC) ANNOUNCES 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 (January 20, 2015) – The International Serious Adverse Events Consortium (iSAEC) announced today another data release from its research efforts designed to discover genetic markers that may predict individuals at risk for serious drug induced adverse events (SAEs). To date, the iSAEC has released anonymous clinical and genotyping data on almost 4,500 cases and controls, covering drug induced liver, skin/hyper-sensitivity, cardiac, agranulocytosis, kidney and pancreatic injury. The iSAEC is a nonprofit research corporation, launched in the fall of 2007, now in its second phase of research, comprised and funded by leading pharmaceutical companies and the Wellcome Trust. The U.S. Food and Drug Administration (FDA) also contributes scientific and strategic input into this novel research effort.

The current data release includes anonymous clinical and genotyping data on 376 SAE cases. 146 cases relate to 5-Aminosalicylate induced nephrotoxicity. 230 cases relate to Thiopurine induced pancreatitis. Both research studies were conducted in conjunction with Tariq Ahmad, MD, PhD, and Professor of Gastroenterologist and Graham Heap, MD at the Royal Devon & Exeter Hospital in England. Nephrotoxicity is a rare idiosyncratic reaction to 5-aminosalicylate (5-ASA) therapies. 5-ASA medications are the most frequently prescribed class of drug to induce and maintain remission in patients with mild-to-moderately active ulcerative colitis. Pancreatitis is a serious adverse effect of several drug therapies and occurs in approximately 4 to 7% of patients treated with the thiopurines azathioprine or mercaptopurine. The drugs, which include azathioprine and mercaptopurine, are some of the most effective and most commonly used drugs to suppress the immune system in the treatment of Inflammatory Bowel Disease (IBD), rheumatoid arthritis and after some organ transplants. The development of pancreatitis is unpredictable and almost always leads to drug withdrawal. The 5-ASA nephrotoxicity study has been submitted for publication, while the Thiopurine induced pancreatitis results were published late last year. *("HLA DQA1-DRB1 variants confer susceptibility to pancreatitis induced by the thiopurine immunosuppressants". Graham A. Heap, Tariq Ahmad et al., doi:10.1038/ng.3093, Nature Genetics, 15 September, 2014.)*

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. There are a large number of drugs that can cause livery injury or skin rashes in a small subset of patients. Although the exact mechanisms behind such rare and unpredictable serious adverse reactions are unknown, research suggests a genetic contribution.

These data can be accessed via the iSAEC'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.

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 SAE research/operations. The iSAEC's 10 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. 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 iSAEC studies and data release.

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About the iSAEC
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 this research. The iSAEC is the only privately-funded partnership currently dedicated to studying SAE genomics.