



**Contact: Arthur Holden**

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

**iSAEC AND CATHOLIC HEALTH INITIATIVES CENTER FOR TRANSLATIONAL RESEARCH COLLABORATE TO FIND GENETIC MARKERS OF DRUG-INDUCED SERIOUS ADVERSE EVENTS**

*The nation's 3<sup>rd</sup> largest faith-based and 6<sup>th</sup> largest overall hospital network partners with innovative international genomics research consortium iSAEC to launch SAENet*

**Chicago (June 22, 2011)** – The International Serious Adverse Event Consortium (iSAEC) announced today a new collaboration with Catholic Health Initiatives Center for Translational Research (CTR) 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 this collaboration, the iSAEC will partner with the CTR to leverage its research capabilities and clinical data warehouses, to build research cohorts associated with the genetics of three initial drug-induced SAEs: hepatotoxicity; serious skin rashes; and acute hypersensitivity syndrome. The CTR is a business unit of Catholic Health Initiatives Institute for Research and Innovation which supports translational research activity within Catholic Health Initiatives' (CHI's) network of 73 hospitals, spanning 19 states.

This collaboration will provide a foundation for SAENet, a new US-based SAE research initiative being developed by the iSAEC. SAENet is a network being developed of US based large teaching and community based hospitals to secure well characterized SAE cases for biomedical research into the genetic basis of adverse drug responses. The first phase of the CTR collaboration is expected to run for approximately 24 months.

“Our efforts to date on drug induced immunologic SAEs traditionally leveraged academic networks with research subject recruitment across a limited number of hospitals,” said Arthur L. Holden, Chairman of the iSAEC. “By working with the CTR and other large sophisticated providers, all of whom have outstanding clinical research capabilities, we hope to open up a new, more scalable research channel for enrollment of subjects into this vital research. Our goal is to increase the breadth and diversity of patient participation to provide our clinical research collaborators with larger, more developed research cohorts in a more efficient and effective manner.”

“The CTR is excited to work with iSAEC on such an important project. Serious adverse events are real and often life threatening problems encountered by patients,” said Jeffrey M. Otto, PhD, MBA National Director of the Center for Translational Research. “Initiatives such as this one clearly support our objective of bringing state-of-the-art research to patients in our communities.”

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 information technology (IT) infrastructure is located at its data analysis and coordination center at Columbia University in 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](http://www.saeconsortium.org), [www.saeconsortium.org](http://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 iSAEC and support of research data release.

### **About Catholic Health Initiatives**

CHI is a national nonprofit health organization with headquarters in Englewood, Colo. The faith-based system operates in 19 states and includes 72 hospitals; 40 long-term care, assisted- and residential-living facilities; two community health-services organizations; and home health agencies. In fiscal year 2010, CHI provided almost \$590 million in charity care and community benefit, including services for the poor, free clinics, education and research. With annual revenues of approximately \$9 billion, CHI is the nation's third-largest Catholic health care system.

### **About the Center for Translational Research**

The Center for Translational Research (CTR) is an emerging participant and partner in the realization of biomarker-driven personalized medicine. Based in Towson, MD, the CTR is a national laboratory that leverages its molecular diagnostic CLIA laboratory, biospecimen procurement network and repository, and development capabilities to enable improved treatment options for patients. The CTR further acts as an innovation catalyst for CHI by focusing on personalized medicine in the healthcare setting. The Center for Translational Research is part of Catholic Health Initiatives and is a Colorado limited liability company whose sole corporate member is Catholic Health Initiatives Institute for Research and Innovation (CIRI).

# # #