NEWS RELEASE
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FDA Press Office: 301-796-4540
Consumer Inquiries: 888-INFO-FDA
SAEC Inquiries: 773-867-8595

FDA and International Serious Adverse Events Consortium Release First Data on Genetic Basis of Adverse Drug Events

The first data offering health care professionals a better look into the genetic basis of certain types of adverse drug events was released today by the FDA and the International Serious Adverse Event Consortium (SAEC). The data are focused on the genetics associated with drug-induced serious skin rashes, such as Stevens-Johnson syndrome and toxic epidermal necrolysis, and helps better predict an individual's risk of developing these reactions.

Both skin conditions appear as allergic-like skin reactions associated with blistering and peeling, and are considered life-threatening. Medications causing these serious allergic reactions should be discontinued; and if such signs and symptoms are not quickly recognized, these reactions can be fatal.

"The SAEC has fulfilled a key goal of the Critical Path Initiative by providing the research community with public access to new genomic data on adverse drug events," said Janet Woodcock, M.D., director, the FDA's Center for Drug Evaluation and Research. "This consortium has taken a significant step forward by promoting open sharing of drug safety data. This type of cooperation has the potential to lead to more personalized approaches to medicine that can reduce a patient's risk for experiencing an adverse drug event."

The SAEC is a nonprofit partnership of pharmaceutical companies, the Wellcome Trust, and academic institutions focused on research relating to the genetics of drug-induced serious adverse events. The samples from the initial serious skin rash cases and matched controls were collected by GlaxoSmithKline plc, London, U.K., and donated to the consortium for this research.

By pooling these samples, the SAEC has identified numerous genetic associations that may contribute to an individual's risk of developing serious drug-induced skin reactions. The data was compiled and analyzed just 16 months after the consortium was launched.

"We are pleased to be able to provide these invaluable data to the research community to both improve the productivity of drug development and to begin the critical process of developing validated biomarkers to forecast patients who may be at risk for drug-induced

serious adverse events," said Arthur Holden, founder and chairman of the SAEC. "We continue to believe the application of genomics to research the genetic basis of serious adverse events will prove to be one the most productive early applications of this technology."

The consortium will publish its initial research results later this year.

Researchers who enter in to a data use agreement can obtain free access to the data to generate custom data inquiries and obtain immediate results on the genetic basis of adverse drug events.

For more information on the International Serious Adverse Event Consortium see www.saeconsortium.org.

For information on the FDA's Critical Path Initiative see http://www.fda.gov/oc/initiatives/criticalpath/