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ILSI Health and Environmental Sciences Institute

## **HESI Announces Submission of Renal Biomarker Qualification Data to FDA and EMEA**

**May 6, 2008**

The HESI Committee on the Application of Biomarkers of Toxicity, Nephrotoxicity Working Group, is pleased to announce the May 1, 2008, submission of a renal biomarker VXDS (Voluntary eXploratory Data Submission) to the FDA and EMEA. This unique data package represents the outcomes of a joint effort of multiple pharmaceutical companies, academia, and government scientists to collaboratively design studies for the purpose of biomarker qualification. The samples, data, and analysis were validated across multiple laboratories over a period of several years.

According to Dr. Janet Woodcock, Director of Center for Drug Evaluation and Research at the FDA, "The FDA is pleased to receive the Biomarker Qualification Data Submission (BQDS) from HESI. The multi-laboratory study data generated by the HESI Biomarkers Committee represent an important contribution to the biomarker qualification process. FDA recognizes the significant effort that went into generating these data and that they represent the outcomes of the first prospectively and collaboratively designed, executed, and analyzed qualification studies submitted as part of the BQDS process. The HESI BQDS data set is one of only 4 ever submitted to the FDA."

These preclinical studies, which point to renal markers that may augment sensitivity and/or specificity over those used most commonly, demonstrate the scientific value of a collaborative approach to study design, execution, and interpretation.

The data are provided to the FDA in support of the FDA's Critical Path to New Medical Products that calls for the development of new predictive safety biomarkers to "improve the effectiveness of safety screening prior to introducing products into humans, enable better selection of initial human doses, and help target toxicity monitoring in early trials."

The HESI VXDS supports the biological qualification of a number of novel biomarkers in comparison with reference biomarkers - including the most widely used urinary biomarkers (NAG and protein). The biological qualification also includes a technical evaluation of immunoassays for the novel urinary markers RPA-1, GST- $\alpha$  and GST- $\mu$ , and clusterin. The study incorporated cross-laboratory biological evaluation of the performance of these markers with three different nephrotoxic compounds and two rodent strains.

Representatives from the Committee will discuss the data package with the FDA and EMEA at a joint meeting on July 2, 2008. Following this meeting, the Agencies will release a determination as to whether and for which uses the markers described in the HESI report are 'qualified'.

HESI is a non-profit scientific organization that brings together academic, industrial, and government scientists to address and reach consensus on scientific questions around human health, toxicology, risk assessment, and the environment. HESI was established in 1989 as a global branch of the International Life Sciences Institute. More information on HESI is available at [www.hesiglobal.org](http://www.hesiglobal.org) or via email at [hesi@hesiglobal.org](mailto:hesi@hesiglobal.org).