

## The FNIH Biomarkers Consortium Launches Project to Improve Diagnosis of Kidney Injury

*Researchers aim to advance acceptance of new biomarkers for monitoring kidney safety in the clinic*

Bethesda, MD (November 1, 2011) – The Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium announced today the launch of a two-year clinical study aiming to advance the acceptance of new biomarkers designed to detect drug-induced kidney injury in clinical trials. The study is being conducted in collaboration with the Predictive Safety Testing Consortium (PSTC), a public-private partnership founded by the Arizona-based non-profit Critical Path Institute (C-Path).

The potential toxic effect of some medications on the kidney – or drug-induced nephrotoxicity – can be a serious problem for drug developers. The current standard biomarkers used to detect acute kidney injury are not sensitive enough and can produce false positive results; sometimes forcing researchers to abandon otherwise promising drug candidates. The FNIH Biomarkers Consortium Kidney Safety project is designed to test new biomarkers that are more sensitive, and will establish better criteria for when kidney safety concerns should halt further testing of a drug in humans.

"Patient safety is and must be our primary concern as we develop potential new medicines," explained Gary Herman, M.D., Vice President, Early Stage Development at Merck Research Laboratories. "The FNIH Biomarker Consortium Kidney Safety project is critical to help identify biomarkers that improve the process of developing effective medicines that are safe to test and use with patients."

The clinical studies will be conducted at four major U.S. medical research centers: the University of Southern California, the University of Minnesota, the Brigham and Women's Hospital/Dana Farber Cancer Institute and the MD Anderson Cancer Center. Blood and urine samples will be collected from patients undergoing treatment with two different drugs known to cause injuries to the kidney tubule; cisplatin, a common type of chemotherapy drug taken by patients with head and neck cancer, and aminoglycosides, a common type of antibiotic drug taken by patients with cystic fibrosis.

The project will enable the continued development of potentially valuable compounds across a number of therapeutic areas, such as cancer, cystic fibrosis and diabetes. The data generated from this project is aimed to advance regulatory acceptance of new biomarkers appropriate for monitoring kidney safety in the clinic. Importantly, this data will improve clinical diagnoses of drug induced kidney injury during drug development and patient therapy.

"We need better ways of predicting potential kidney injury from new therapies early on in the development process," said Janet Woodcock, M.D., Director of the Center for Drug Evaluation Research at the U.S. Food and Drug Administration. "The Biomarkers Consortium project represents a powerful collaborative approach to qualifying the biomarkers needed to accomplish this."

The studies, managed by the FNIH Biomarkers Consortium, will build significantly on previous work to qualify kidney safety markers for use in animal studies conducted by the PSTC. The PSTC and C-Path are also providing healthy volunteer data, database, and biorepository services to support the Biomarkers Consortium effort. The project, led by Frank Sistare, PhD, of Merck Research Laboratories, will also include participation of a diverse group of experts from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH), the Food and Drug Administration (FDA), several pharmaceutical companies, and academic organizations. Participating and funding organizations include Amgen, AstraZeneca, C-Path, Eli Lilly & Company, Johnson & Johnson, Merck Research Laboratories, and Pfizer.

For more information about this project, please visit [www.biomarkersconsortium.org](http://www.biomarkersconsortium.org) or [www.fnih.org](http://www.fnih.org)

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### **About the Foundation for the NIH**

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### **About the Biomarkers Consortium**

The Biomarkers Consortium is a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH) that endeavors to develop, validate, and/or qualify biological markers (biomarkers) to speed the development of medicines and therapies for detection, prevention, diagnosis and treatment of disease and improve patient care. For additional information about the Biomarkers Consortium, please visit [www.biomarkersconsortium.org](http://www.biomarkersconsortium.org)