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Foundation for the NIH Launches Bone Quality Project
Effort will spur drug development

Bethesda, MD (December 3, 2013) — The Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium announced today the launch of a three-year study to track the progression of osteoporosis more precisely and pave the way for more effective treatments. The study, which utilizes data from existing academic and clinical trials, is designed to establish the validity of specific imaging and biochemical markers for bone health.

Approximately 9 million adults in the United States suffer from osteoporosis, a progressive bone disease that is characterized by a decrease in bone mass and density that leads to an increased risk of bone fractures, and, with our aging population, the numbers continue to rise. Over the last twenty years, progress has been made in both the diagnosis and treatment of osteoporosis. Substantial challenges remain, however, including limited treatment efficacy for non-spine fractures, limited evidence that anti-osteoporosis drugs prevent fractures among those who do not yet have osteoporosis, and lack of data supporting the efficacy of a given treatment beyond the duration of most clinical trials. Recent concerns have prompted regulatory agencies to review the safety of antiresorptive drugs for osteoporosis, while these same concerns among patients and physicians are decreasing the use of this particular class of drugs.

“There is an imperative need for continued development of new osteoporosis drugs and for determining rational clinical strategies for their use,” says Dr. Janet Woodcock from the Food and Drug Administration (FDA). “We applaud the FNIH for spearheading this important work.”

The FNIH Biomarkers Consortium Bone Quality Project will evaluate the effectiveness of two types of biomarkers that measure bone strength: 1) Quantitative Computed Tomography (QCT), a state-of-the-art imaging technology, and 2) biochemical markers of bone turnover (BTM), defined as biomarkers of bone formation or resorption. Both QCT and BTMs have been included in existing clinical trials in small subsets of patients with some relevant analyses previously performed. However, analytic methods have varied greatly among the existing analyses and this challenge, together with small sample sizes, has limited the ability to draw definitive conclusions about their utility.

“This effort has great potential to impact clinical trials and ultimately clinical practice by improving our understanding of these imaging and biochemical biomarkers in patients with osteoporosis,” says Dr. Stephen I. Katz, Director of the NIH’s National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS).

“The Bone Quality Project will take advantage of the many thousands of patients who have already been studied over the years in both the academic and industry settings by pooling the data from the QCT and BTM sub-studies to conclusively establish the value of these measurements for drug development and clinical use,” said Dr. Dennis Black, the Principal Investigator from the University of California San Francisco (UCSF). Black will lead the project along with Drs. Douglas Bauer at UCSF and Mary Bouxsein at Harvard Medical School. Utilizing a collaborative approach, the FNIH Biomarkers Consortium has brought together osteoporosis experts from the National Institutes of Health (NIH), FDA, academic institutions, the pharmaceutical industry, and non-profit sector to develop the project. The project chair is Dr. Gayle Lester from NIAMS. Financial support is being provided through funds contributed to the FNIH for this project from the American Society for Bone and Mineral Research, Amgen, Inc., Eli Lilly and Company, Merck & Co., Inc., and the Dairy Research Institute ®.

“This public-private partnership involves key stakeholders in the osteoporosis field to address a critical unmet medical need,” says Dr. Maria Freire, FNIH President and CEO. “The validation of biomarkers for use in patient management will facilitate drug development to treat and potentially prevent this prevalent disease in the growing world population of older adults.”

For more information about this project, please visit www.fnih.org.

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About the Foundation for the NIH

Established by the United States Congress to support the mission of the NIH—improving health through scientific discovery in the search for cures—the Foundation for the NIH is a leader in identifying and addressing complex scientific and health issues. The Foundation is a non-profit, 501(c)(3) charitable organization that raises private-sector funds for a broad portfolio of unique programs that complement and enhance NIH priorities and activities. For additional information about the Foundation for the NIH, please visit www.fnih.org.

About the Biomarkers Consortium

The Biomarkers Consortium is a public-private biomedical research partnership managed by the [Foundation for the National Institutes of Health](http://www.fnih.org) that endeavors to discover, develop, and seek regulatory approval for 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.