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## **The Foundation for the NIH Biomarkers Consortium Begins Development of Patient-Reported Outcome Measures for Community-Acquired Pneumonia and Skin Infections**

Bethesda, MD (April 10, 2013) – The Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium has launched a research collaboration to develop new Patient-Reported Outcome measures (PROs) to better evaluate the effectiveness of treatments for common, serious skin infections and community-acquired bacterial pneumonia, or CABP. Developing the new measures is particularly critical given the need for new medicines to treat emerging drug-resistant strains of these infections, which have been on the rise around the world.

Acute bacterial skin infections are increasingly caused by antibiotic-resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA). Drug-resistant pathogens have also been implicated in community-acquired bacterial pneumonia, a leading cause of death in the United States with approximately one million episodes occurring annually in adults 65 years of age and older. Drug researchers and regulatory agencies currently lack reliable, well-defined clinical measurements of how patients feel and function during treatment with antibacterial drugs for these important infections. The measures developed through the Biomarkers Consortium will enable researchers to design more effective clinical trials of these new drugs and speed the path to their approval.

"Thanks to the leadership of the FNIH and The Biomarkers Consortium, the scientific community is now working toward the development of well-defined and reliable endpoints for bacterial pneumonia and acute bacterial skin and skin structure infections," said Janet Woodcock, M.D., director of the U.S. Food and Drug Administration's Center for Drug Evaluation and Research. "As a founding member of The Biomarkers Consortium, the FDA works closely with experts to rapidly identify, create and qualify biomarkers that we hope will be successful in helping develop innovative new drugs."

The collaboration brings together scientists from the FDA, the NIH National Institute of Allergy and Infectious Diseases, the NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases, the NIH National Institute of Nursing Research, the Infectious Diseases Society of America, pharmaceutical and biotechnology companies, and the academic research community. The collaboration has already made significant progress in developing skin infection PROs, and plans to complete development of new measures in both diseases by the middle of 2014.

Scientific and financial support for this project has been provided by the Pharmaceutical Research and Manufacturers of America (PhRMA), and by individual companies including Actelion Pharmaceuticals, AstraZeneca, Basilea Pharmaceutica International Ltd., Cempra Pharmaceuticals, Cerexa Inc. (a wholly-owned subsidiary of Forest Laboratories, Inc.), Cubist Pharmaceuticals, Durata Therapeutics, Merck, Nabriva Therapeutics, and Trius Therapeutics, Inc. Clinical trial data were contributed to the collaboration by Cerexa and Cubist, and Pfizer, Inc. Oxford Outcomes, a leading international health outcomes consultancy group, was selected to provide expertise on PRO instrument development and qualitative research methodology for the effort.

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**

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](http://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](http://www.biomarkersconsortium.org).