

## **New Project Led by the Foundation for the NIH Biomarkers Consortium Will Have Significant Impact On the Development of New Antibiotics**

Bethesda, MD (February 7, 2012) – The Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium has launched a research collaboration that aims to remove obstacles to developing new antibacterial treatments for common, serious skin infections and community-acquired bacterial pneumonia, or CABP. Acute bacterial skin infections are increasingly caused by bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA), for which only a handful of effective oral medications are available. Community-acquired bacterial pneumonia is a leading cause of death in the United States, with approximately one million episodes occurring annually in adults 65 years of age and older.

The collaboration brings together scientists from the Food and Drug Administration (FDA), the National Institute of Allergy and Infectious Diseases, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Nursing Research, the Infectious Diseases Society of America, pharmaceutical and biotechnology companies, and the academic research community to develop new regulatory standards for judging the efficacy of antibiotics in future clinical trials of therapies for skin infections and CABP. This project is particularly important given the need for new medicines to treat emerging drug-resistant strains of skin infection and CABP pathogens, which have been on the rise around the world.

A significant challenge in obtaining new antibiotic drug approvals is that the endpoints, or outcome measures, that FDA uses to judge the success of “non-inferiority” clinical trials in these infections (trials that are designed to determine whether a new antibiotic is comparably effective to a current standard antibiotic treatment) are based on research studies that date back half a century or more. As a result, FDA approval of new drugs for these infections has been seriously hampered, discouraging pharmaceutical and biotechnology companies from continuing to invest in new antibiotic development efforts.

The FNIH scientific team has already achieved significant progress. Having assembled and analyzed historical studies as well as data from modern clinical trials, the group recently submitted recommendations regarding interim clinical trial endpoints to the FDA. These interim recommendations will facilitate clinical drug development programs being conducted now; a second phase plans to further refine the understanding of the endpoints and develop and test new methods for measuring them.

"The work of the FNIH Biomarkers Consortium highlights the importance of reevaluating clinical trial endpoints used to approve drugs for new and emerging public health issues. FDA embraces its role in facilitating drug development and looks forward to its continued collaboration with this important initiative said," Dr. Janet Woodcock, M.D., Director of the Center for Drug Evaluation Research at the FDA.

Scientific and financial contributions in support of this project have been provided by Actelion Pharmaceuticals, AstraZeneca, Basilea Pharmaceutica International, Cempra Pharmaceuticals, Cerexa Inc., a wholly-owned subsidiary of Forest Laboratories, Inc., Cubist Pharmaceuticals, Merck, Nabriva Therapeutics and Trius Therapeutics, Inc. Clinical trial data were also contributed to the collaboration by Cerexa and Cubist, as well as by Durata Therapeutics and Pfizer, Inc.

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](#) 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).