

**FOR IMMEDIATE RELEASE**

**TB Alliance and BG Medicine Initiate Biomarker Discovery Program**

*Project Aims to Streamline and Shorten Drug Development for Tuberculosis*

**New York, NY and Waltham, MA., February 21, 2006** – The Global Alliance for TB Drug Development (TB Alliance) and BG Medicine Inc. announced today a collaboration to identify biomarkers for drug efficacy in the treatment of tuberculosis (TB), a step toward faster and more efficient drug development.

“The clock is ticking, we need to find a faster cure for TB, and new biomarkers could expedite our search,” said Dr. Maria C. Freire, President and CEO of the TB Alliance. “Clinical trials for TB drugs are especially time-consuming so a new biomarker that helps us test novel medicines faster and more efficiently will be a tremendous asset in developing a better, affordable TB cure.”

Today, clinical trials for TB drugs are based on standard treatment regimens requiring 6-9 months of therapy, with efficacy evaluation taking another 1-2 years to measure relapse rates in those patients who have not been successfully cured. In total, clinical trials required to register a TB drug can take a minimum of six years, much longer than trials for other infectious diseases. The result is high drug development costs and long delays in introducing new medicines. The identification of biomarkers could streamline and accelerate the process.

“This project demonstrates the broad applicability of the systems approach to improving drug development to make novel and improved therapies available sooner,” said Pieter Muntendam, MD, President and CEO of BG Medicine. “Biomarkers offer a more predictable and less costly avenue in product development; nowhere is this more badly needed than in developing drugs for TB.”

A biomarker is a quantifiable biochemical characteristic -- such as a metabolite, hormone or enzyme -- that is measured and evaluated as a pharmacologic response to therapy. Biomarkers can be particularly useful in clinical trials to predict a person’s response to a compound and in some cases serve as the basis of a surrogate endpoint. Having such markers facilitates decision-making in the drug development process, enabling earlier decisions, for example, as to whether to terminate a compound’s development or advance it into late stage clinical trials.

The TB Alliance and BG Medicine will apply systems approaches to identify biomarkers for two purposes: first, to provide an early indication of a drug’s ability to shorten treatment time during Phase II testing; and, second, to act as a surrogate marker of treatment efficacy that would shorten Phase III trials and eliminate the need to follow patients for up to two years post-therapy to determine relapse rates.

The TB Alliance and BG Medicine are conducting this six-month study in collaboration

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with Colorado State University (CSU). CSU, with their expertise in TB animal model drug testing, is providing the samples that will be analyzed by BG Medicine through their proteomic and metabolomic analytical platforms. Funding for both BG Medicine and CSU is provided by the TB Alliance. The study is made possible through a grant from the Department of Development Cooperation of the Netherlands Ministry of Foreign Affairs (DGIS), the leading Dutch government agency for foreign assistance.

TB affects one-third of the world's population, resulting in nine million new cases of active disease and two million deaths each year. TB is caused by a slow-growing bacterium that most commonly damages the lungs, although it can infect any organ. Unlike many microbes, it can live inside the body for decades before causing illness.

Current projections of TB incidence and mortality reflect the need for shorter, more effective TB therapy. An estimated 1 billion people will be newly infected between 2000 and 2020, 200 million will fall ill and 35 million will die. TB is a leading cause of death among people living with HIV/AIDS, and multi-drug resistant strains are spreading at a rate of 300,000 newly diagnosed cases a year. Someone in the world dies of TB every 15 seconds.

#### **About the Global Alliance for TB Drug Development**

The Global Alliance for TB Drug Development (TB Alliance) is a not-for-profit, public-private partnership accelerating the discovery and/or development of affordable, new anti-TB drugs that will shorten treatment, be effective against multi-drug resistant strains, treat HIV-TB co-infection, and improve treatment of latent infection. Working with public and private research laboratories worldwide, it is leading the development of the first, most comprehensive portfolio of TB drug candidates in three decades. It operates with the support of the Bill and Melinda Gates Foundation, the Rockefeller Foundation, the United States Agency for International Development, and the Department of Development Cooperation of the Netherlands Ministry of Foreign Affairs (DGIS). For more information on TB drug development and the TB Alliance, please visit [www.tballiance.org](http://www.tballiance.org).

#### **About BG Medicine**

BG Medicine was founded in 2000 by scientific leaders in systems biology and Flagship Ventures (Cambridge, Ma.) to pioneer commercial applications of Systems Biology. The company's proprietary method of integrating multiple analytical platforms including proteomics and metabolomics with powerful bioinformatics and computational analysis allows BGM to discover biomarkers that can both shorten drug development times and reduce attrition of drugs in later-stage trials. Several leading pharmaceutical companies are currently utilizing BG Medicine's services to correlate various disease effects with new classes of drugs. The U.S. Food and Drug Administration is also partnering with BG Medicine to predict human liver toxicity in the drug development process. For more information about BG Medicine please visit [www.BG-Medicine.com](http://www.BG-Medicine.com).

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