Public-Private Partnership Announces Immediate 40 Percent Cost Reduction for Rapid TB Test

PEPFAR, USAID, UNITAID and Bill & Melinda Gates Foundation have finalized an agreement to expand access to GeneXpert®, a molecular diagnostic system that provides a two-hour rapid diagnosis of TB, TB/HIV co-infection and drug-resistant TB.

Contact:

Gates: media@gatesfoundation.org PEPFAR: padmanabhana@state.gov

UNITAID: unitaid@who.int

USAID: usaidpressofficers@usaid.gov

WASHINGTON – August 6, 2012 – Today, the United States President's Emergency Plan for AIDS Relief (PEPFAR), the United States Agency for International Development (USAID), UNITAID, and the Bill & Melinda Gates Foundation announced an agreement that will significantly reduce the cost of a new, highly accurate, rapid diagnostic test for tuberculosis (TB).

Funds provided by this partnership will reduce the cost of Xpert MTB/RIF cartridges from \$16.86 to \$9.98, a price which will not increase until 2022. The effective date of this price decrease is August 6, 2012.

To date, the high unit cost of Xpert® MTB/RIF cartridges produced by the medical device manufacturer Cepheid has proven a barrier to their introduction and widespread use in low- and middle-income countries. The new agreement will immediately reduce the cost of cartridges used to diagnose TB by more than 40 percent in 145 high-burden and developing countries worldwide.

In December 2010, the World Health Organization (WHO) recommends the Cepheid product, known as Xpert MTB/RIF assay, which is run on Cepheid's GeneXpert platform. Until Cepheid developed the Xpert MTB/RIF assay, the only method used in most laboratories in developing countries was smear microscopy, a technique first developed in the 1880s by the German bacteriologist Robert Koch that requires visual detection of the TB bacterium under a microscope.

Smear microscopy is particularly insensitive for diagnosing TB in patients who are co-infected with HIV. It also does not help clinicians detect the presence of drug-resistant strains of TB. The limitations of traditional smear microscopy, along with the cost and long delays to receive culture results, have limited the ability to diagnose and treat TB and drug-resistant forms of the disease.

Cepheid's GeneXpert is a molecular diagnostic system that can detect TB disease in patients co-infected with HIV and resistance to the antibiotic rifampicin – a widely accepted indicator of the presence of multi-drug resistant TB – in less than two hours. The system also can be used outside of conventional laboratories because it is self-contained and does not require specialized training.

Because TB is the leading cause of death among people living with HIV in Africa, greater access to this test offers a significant advance in the capacity of health care workers to diagnose TB quickly and help reduce TB transmission, the development of TB disease, and premature TB deaths.

The capacity of the Xpert MTB/RIF assay to yield a rapid and accurate diagnosis has the potential to improve TB diagnosis and treatment in rural clinical settings. A large percentage of people with TB disease fail to start treatment promptly because of the long wait for results of older conventional tests and the need for them to return to the clinic, which may be far from where they live. Using the GeneXpert system, clinics in poor and rural settings can deliver rapid diagnosis and immediately start patients on appropriate treatment, including

second-line drugs in cases of drug-resistant.

Research suggests that the incremental scale up of GeneXpert in countries with high TB burdens could allow for the rapid diagnosis of 700,000 cases of TB disease and save health systems in low- and middle-income countries more than U.S. \$18 million in direct health costs.



The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) is the U.S. Government initiative to save the lives of those affected by HIV/AIDS around the world. This historic commitment is the largest by any nation to combat a single disease internationally, and PEPFAR investments also help alleviate suffering from other diseases across the global health spectrum. PEPFAR is driven by a shared responsibility among donor and partner nations and others to make smart investments to save lives. For more information about PEPFAR, visit www.PEPFAR.gov



USAID carries out U.S. foreign policy by promoting broad-scale human progress at the same time it expands stable, free societies, creates markets and trade partners for the United States, and fosters good will abroad. Spending less than one-half of 1 percent of the federal budget, USAID works in over 100 countries to: promote broadly shared economic prosperity; strengthen democracy and good governance; improve global health, food security, environmental sustainability and education; help societies prevent and recover from conflicts; and provide humanitarian assistance in the wake of natural and man-made disasters. For more information, go to www.usaid.gov.



UNITAID is a global health initiative launched in 2006 by the Governments of Brazil, Chile, France, Norway and the United Kingdom to provide sustainable funding for the fight against HIV/AIDS, malaria and tuberculosis. About 70% of UNITAID's funds come from a small levy on airline tickets. Through implementers, UNITAID finances the purchase of quality-assured drugs and diagnostics for patients in poor countries, using its market power to expand supply, promote development of new and better products, cut delivery lead times and reduce prices. For more information, go to www.unitaid.eu.

BILL & MELINDA GATES foundation

Guided by the belief that every life has equal value, the Bill & Melinda Gates Foundation works to help all people lead healthy, productive lives. In developing countries, it focuses on improving people's health and giving them the chance to lift themselves out of hunger and extreme poverty. In the United States, it seeks to ensure that all people—especially those with the fewest resources—have access to the opportunities they need to succeed in school and life. Based in Seattle, Washington, the foundation is led by CEO Jeff Raikes and Co-chair William H. Gates Sr., under the direction of Bill and Melinda Gates and Warren Buffett. For more information, visit www.gatesfoundation.org.