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We have largest portfolio of new TB drugs'

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The Global Alliance for TB Drug Development (TB Alliance) is a non-profit organization dedicated to the discovery and development of new, faster-acting and affordable tuberculosis medicines. In an interview with *BioSpectrum*, Dr Mel Spigelman, president & CEO, TB Alliance, speaks about the initiatives taken by TB Alliance and its future plans.

What are the areas of focus for TB Alliance?
TB Alliance has developed and is currently managing the largest portfolio of potential new TB drugs. This portfolio includes more than 20 drug discovery and development programs, including three drug candidates in late-stage clinical trials, the first-ever clinical trial testing multiple new TB drug candidates simultaneously, in combination, and preclinical discovery and screening programs that encompass thousands of compounds being screened, synthesized, or optimized in discovery and preclinical studies. The objective is to bring out an entirely novel therapeutic regimen that will shorten and simplify treatment.

A faster, better TB drug regimen will improve patient compliance, increase cure rates, lower toxic side-effects, and could save millions of lives. As new treatments are developed, the TB Alliance hopes to bring down the time taken to cure TB from the average six-month period for finishing the treatment. The long-term goal of TB Alliance is to find out a treatment option that can be administered in less than two weeks, similar to those for many other bacterial infections.

Can you shed light on some of TB Alliance's initiatives?
In addition to the pipeline of new drug candidates, the TB Alliance is leading a number of initiatives to benefit the field of TB at large, including a consortium dedicated to discovering and developing reliable biomarkers. Additionally, the TB Alliance is co-

founder of The Critical Path to TB Drug Regimens (CPTR), which is a broad collaboration of pharmaceutical companies, civil society organizations, and others working to overcome a wide variety of challenges to drug development, with the goal of dramatically accelerating the development of new, safe, and highly-effective combination treatments for TB. CPTR partners include many of the world's leading pharmaceutical developers. The TB Alliance leads the Drug Development Coalition, which is one of the three arms of CPTR.

How does TB Alliance operate?
The TB Alliance operates with funding from the Bill & Melinda Gates Foundation, the UK Department for International Development (DFID), the European Commission, the US Agency for International Development (USAID) and the US Food and Drug Administration. Other fund providers over the past decade include Irish Aid, the Netherlands Ministry of Foreign Affairs and the Rockefeller Foundation.

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Through their funding, our donors have contributed to the assembly and management of the largest TB product portfolio in history, including several promising innovative TB drug regimens, three new drugs in regimen development, and more than 25 projects in the portfolio. By investing in TB drug development and efforts to reverse the global TB epidemic, donors are promoting increased global health as well as prosperity, given that TB is a tremendous barrier to economic development for many of the nations hardest hit by the disease.

What are the new initiatives in the pipeline?
The TB Alliance has led the development of the most comprehensive portfolio of TB drug candidates in history. The portfolio includes one TB drug candidate (moxifloxacin) in phase III testing, two others (PA-824 and TMC-207) in phase II trials and 20 additional projects in various stages of discovery and development.

Moxifloxacin is being studied to test whether a four-drug combination regimen including moxifloxacin can reduce treatment time for drug-sensitive disease from six to four months. PA-824, the first novel TB drug candidate developed by a non-profit to reach clinical trials, shows promise for the treatment of drug-sensitive and drug-resistant TB. TMC-207 is undergoing parallel clinical testing for both drug-sensitive and drug-resistant indications.

In 2010, the TB Alliance launched the first clinical trial testing multiple novel TB drug candidates simultaneously, in combination. Going forward, we see this as the dominant paradigm of TB drug development and we plan to continue working to assemble and develop multi-drug regimens with the potential to treat both drug-sensitive and drug-resistant TB, quickly, effectively, and inexpensively.

What are your views on the TB-related R&D activities in Asia?
Some of the highest burden TB countries are in Asia (including Bangladesh, China, India, Indonesia, Pakistan, the Philippines, Thailand, and Vietnam), so there is a critical need for intensifying TB-related R&D in Asia.

The TB Alliance is encouraged by the steps taken by some countries in Asia to increase TB control measures. China has been able to lower their TB burden substantially over the past decade. Still, TB, MDR-TB, and TB-HIV coinfection remain substantial public health issues in many countries throughout the region.

The TB Alliance's riminophenazines program, which is a collaboration with Institute of Materia Medica, Chinese Academy of Medical Sciences was awarded funding from the Chinese government in 2009, which the TB Alliance saw as a very encouraging sign, indicating that the Chinese government and others may be interested in becoming true partners in the pursuit of addressing TB and other neglected diseases.