CPTR Yields Progress: New Five-Way Agreement Among Pharmas and NGOs will Speed Development of TB Drug Combinations

- AstraZeneca, Bayer, Sanofi, Tibotec, TB Alliance, and the World Health Organization sign partnership to share information on TB drugs in development
- FDA's Dr. Janet Woodcock to keynote CPTR Workshop and highlight the need for regulatory science to advance regimen development for life-threatening diseases.

Washington, D.C., 9 November 2011 – The Critical Path to TB Drug Regimens (CPTR) today announced an innovative agreement between AstraZeneca, Sanofi, Tibotec, TB Alliance, and the World Health Organization to share information on tuberculosis (TB) compounds within their respective drug pipelines to quickly identify and work together to develop the most promising TB drug regimen, regardless of sponsor. Previously, development of new TB regimens could take decades. The partnership facilitates a more collaborative approach to TB drug development, which can dramatically speed the development of shorter, safer, and more effective multi-drug treatments that are urgently needed to control the global TB pandemic.

The partnership was developed through the Critical Path to TB Drug Regimens (CPTR), a cross-sector initiative that brings together the world's leading pharmaceutical companies, regulatory agencies, and civil society organizations to expedite testing of promising TB drug regimens and identify the new regulatory pathways and other tools needed to speed the delivery of dramatically improved treatment to TB patients worldwide. Co-founded by the Bill & Melinda Gates Foundation, the Critical Path Institute, and the TB Alliance, CPTR is fostering collaboration around an urgent public health need to reduce the time it takes to develop novel TB drug regimens.

"This partnership demonstrates CPTR's potential to transform the way we approach TB drug development," said Hans-Georg Eichler, MD, MSc, Senior Medical Officer, European Medicines Agency, and Chair of CPTR's Advisory Panel. "It is critical that we modernize TB treatment in order to control the global epidemic."

Due to the resilient nature of the bacterium, TB treatment requires multi-drug regimens. Traditional regimen development meant that each new drug had to be tested and approved separately and then substituted or added—one at a time—into existing drug combinations. Each drug trial can last six years or longer, which means that a novel TB regimen could take decades to develop.

"New regimens that are effective against drug-susceptible and drug-resistant TB are urgently needed," said Mario Raviglione, MD, Director of the Stop TB Department, World Health Organization. "Through partnerships like this one, CPTR is supporting the development of new weapons to fight TB and save lives."

The agreement announced today will facilitate information-sharing around scientific and clinical data on TB compounds in clinical development. By sharing data, partners can identify opportunities to test their compounds in combination, speeding availability of future TB regimens. The collaboration

includes the majority of global sponsors with TB drugs in clinical development. Under the agreement, if two or more organizations choose to work together to further develop a regimen, they will enter into a separate arrangement that defines the rights and responsibilities of each party.

“This initiative is a further example of industry working together and with others to share knowledge and expertise for the benefit of the wider society,” said David Brennan, Chief Executive Officer of AstraZeneca. “Working in collaboration, we have a real chance to make a difference in the lives of the millions of people who suffer from TB by contributing the most promising components from our respective pipelines to deliver new, effective treatments for this neglected disease faster.”

CPTR is working closely with regulatory scientists at the U.S. Food and Drug Administration, European Medicines Agency and other regulatory bodies in China, India, and some countries in Africa to develop the tools that are needed to allow testing of new TB drugs in combination, cutting years off the development timeline. Under the leadership of the Critical Path Institute, CPTR’s Regulatory Science Consortium focuses on establishing consensus on preferred standards, methods, and tools for developing new TB drug regimens, and obtaining official acceptance from international regulatory authorities.

“Innovative partnerships are critical to speed development of new TB treatments,” said Dr. Janet Woodcock, Director of the FDA’s Center for Drug Evaluation and Research. “To support co-development, global regulatory systems need to continue to evolve to support new drug development paradigms and ensure lifesaving treatments rapidly reach those who need them most.”

Today’s announcement coincides with a two-day CPTR workshop in Washington D.C. with participants from industry, civil society, government, and regulatory authorities. Dr. Woodcock delivered the keynote address.

TB is one of the world’s deadliest infectious diseases. Although it is often thought of as a disease of the past, TB still kills approximately 1.4 million people in 2010, mainly in developing countries. Treatment for TB requires patients to take medicine for six to 24 months or longer. The long duration of treatment and serious side effects make it difficult for patients to stay compliant, contributing to the spread of drug resistance, which is far more difficult and expensive to treat.

“Today’s announcement will accelerate efforts to simplify and improve TB drug regimens,” said Dr. Mel Spigelman, President and CEO of the TB Alliance. “It is critical that we decrease the complexity and duration of treatment, make the treatment of multi-drug resistant TB significantly easier and more tolerable and make new regimens available to all those who need them as quickly as possible.”

About Critical Path to TB Drug Regimens

The Critical Path to TB Drug Regimens (CPTR) is a cross-sector initiative that aims to speed the introduction of shorter, safer, more effective new TB drug regimens. This effort brings together leading international pharmaceutical companies, public health experts, civil society organizations, and U.S. and other regulatory authorities to: 1) expedite testing of promising TB drug candidates in combination; 2) identify new regulatory pathways and other tools that will accelerate the development process; and 3) deliver dramatically improved treatment to TB patients worldwide. CPTR was co-founded in 2010 by the Bill & Melinda Gates Foundation, the Critical Path Institute, and the TB Alliance to expedite testing of promising TB drug candidates in combination, regardless of sponsor, and to optimize the regulatory and other infrastructure so that new drug regimens are developed, approved, and made available to those that need them as quickly as possible. For more information, please visit www.cptrinitiative.org.