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First Effort to Synthesize and Optimize Quinolones for New, Better TB Treatment Launched

Global Alliance for TB Drug Development to Fund 2-year Project at South Korean Institute & University

April 22, 2003, New York and Seoul – The Global Alliance for TB Drug Development (TB Alliance) announced it will fund a two-year project to synthesize and optimize novel quinolone compounds at the Korean Research Institute of Chemical Technology (KRICT). This is the first time that quinolones, a family of broad-spectrum antibiotics now used to treat drug-resistant TB strains, will be directly explored to become candidates for a new anti-tuberculosis drug.

While TB kills 2 million people a year, the last new class of TB drugs was introduced forty years ago. Under the terms of the agreement with KRICT, the TB Alliance acquires one lead compound in the preclinical stage that has demonstrated activity and specificity for tuberculosis. In addition, the project aims to yield up to three lead candidates to the TB Alliance portfolio for further development. Recent research suggests that quinolones have the sterilizing and bactericidal properties necessary to shorten and simplify first-line therapy.

"The prospect of a potent, first-line quinolone brings us closer to our goal of a better, faster TB treatment accessible to all patients in need," said Dr. Maria C. Freire, CEO of the TB Alliance. "As we bolster the TB Alliance's portfolio of drug candidates, we embark on our first East-Asian partnership and enlist the research and development capacity in regions with a high TB burden."

"Korea is honored to lend its expertise in biology and chemistry as well as our state-of-the-art facilities to help realize the critical public health goal of a faster TB cure," said Dr. Choong-Sup Kim, President, KRICT.

Optimizing Quinolones for TB Treatment

Standard TB treatment today relies on four "first-line" drugs and requires 6-to-9 months to complete. Less than one third of TB patients are currently treated under the international standard treatment protocol. Many patients do not complete treatment, yielding multi-drug-resistant strains (MDR-TB), now spreading at a rate of 400,000 cases a year.

MDR-TB is treated with "second-line" drugs, some of which were not developed specifically for tuberculosis. Treatment takes two years or longer, is more toxic and expensive than standard treatment, but less effective. Quinolones, such as ofloxacin, levofloxacin and ciprofloxacin, are widely regarded as the most effective and best tolerated second-line drugs.

These commercially available drugs have not been optimized for potency and specificity against *Mycobacterium tuberculosis*. Scientists think that a new quinolone that is specific and potent for TB could yield the right dosage, reduce the duration of treatment and improve patient outcome when used as part of first-line treatment.

Potent quinolones would be an achievement in TB drug-discovery and would support TB control efforts by reducing the emergence of drug-resistance, improving patients' therapeutic outcomes, and minimizing side effects.

Terms of the Deal

Under the terms of the agreement, which guarantee equitable access, KRICT will synthesize several hundred novel quinolones for TB treatment. The compounds will then be biologically evaluated, both *in vitro* and *in vivo*, at the Yonsei University College of Medicine in Seoul. The lead compound in the family KRQ-10018 will be further evaluated for efficacy in animal models, toxicology, and pharmacokinetics.

"Dr. Tae-Ho Park and all KRICT's researchers eagerly join the global fight against one of humanity's deadliest infectious foes," said Dr. Kim. "Korea is not immune to TB, and we hope that our contribution in optimizing quinolones will be an asset to TB's challenges, particularly at home."

A faster TB cure would help halt the spread of the epidemic, reduce the costs of treatment by up to 65% and curtail drug-resistance.

In Asia, the TB Alliance works closely with Dr. Yoshiaki Kiso of Japan's Kyoto Pharmaceutical University, who is a member of the TB Alliance Scientific Advisory Committee, in addition to the Japanese Research Institute for Tuberculosis (JATA), the Philippines Coalition Against Tuberculosis (PHILCAT), and Medecins Sans Frontieres – Japan.

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, and improve treatment of latent infection. The TB Alliance builds a portfolio of promising drug candidates, manages their development through cooperative deals with public and private partners, and provides staged funding and expert scientific and management guidance. For more information, visit <u>http://www.tballiance.org</u>.

About KRICT

The Korea Research Institute of Chemical Technology (KRICT) is a non-profit government-supported research institute established in 1976. The main mission of KRICT is to contribute to the advancement of chemical technologies through its research and development activities, academic programs and technical services, and to provide its research results to the chemical industry. For more information, visit <u>http://www.krict.re.kr.</u>

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