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New TB cocktail drug holds great promise

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Singapore: A novel anti-TB drug has generated encouraging results in a recent Phase II trial funded by the non-profit TB Alliance. The combination of three drugs (PA-824, moxifloxacin and pyrazinamide) was able to eliminate 99 percent of the Mycobacterium tuberculosis, the causative agent of tuberculosis (TB), found in patients' saliva following two weeks of treatment.

According to the World Health Organization, TB infects nearly nine million people annually and is responsible for over one million deaths each year. The disease is an escalating medical concern, especially in low-income countries. The new therapy is still in early clinical development, but the results of this Phase II trial show great promise.

The ability of this new drug cocktail to eliminate 99 percent of the bacteria in only two weeks provides a stark contrast to the six-month treatment regimen of TB therapies that is currently on the market. Compliance problems with patients prescribed current TB-related therapy have resulted in the emergence of drug-resistant TB strains, including multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB). A shorter course of therapy is likely to decrease treatment costs while increasing patient compliance.

TB strains resistant to rifampicin and isoniazid are a growing concern, but the new cocktail consists of drugs with different mechanisms of action from both rifampicin and isoniazid, giving it therapeutic leverage against MDR-TB and XDR-TB. The cocktail was effective against both treatment-sensitive and drug-resistant TB in the Phase II trial, but more detailed studies in larger patient populations are required to assess its safety and toxicity profile and efficacy against drug-resistant TB.

Unlike current TB drugs, this cocktail lacks any rifamycins, a drug class known to cause adverse side effects in patients undergoing HIV therapy. HIV patients have an increased likelihood of contracting TB due to their suppressed immune systems, and WHO claims that TB represents a leading cause of morbidity and mortality in HIV patients. For this reason, the global HIV population holds particular interest in any TB therapies in development.

The TB Alliance is a product development partnership between public and private organizations dedicated to developing novel TB therapies. Since its inception in 2000, the TB Alliance has developed the world's largest TB drug portfolio and established connections with stakeholders on a global and national scale. The TB Alliance is, therefore, uniquely positioned to develop and distribute novel TB therapies, such as this promising drug cocktail.

An ongoing phase IIb trial to study the drug cocktail in a larger population over a two-month treatment regimen is being conducted in South Africa, Brazil, and Tanzania. If the trial produces similar results to the Phase II trial, developers will likely attempt to fast-track FDA approval via the GAIN Act, which prioritizes antimicrobial therapies for indications with pressing medical need. Earlier this month, Johnson & Johnson submitted an application for accelerated FDA approval for bedaquiline, a compound with activity against drug-resistant TB.

The novel drug cocktail and Otsuka Pharmaceuticals' delamanid could soon join bedaquiline in the race to become the first novel TB therapy in almost half a century.