

FDA Approves Priftin® For LTBI



FDA has approved Priftin® (rifapentine) for the treatment of latent tuberculosis infection (LTBI).

Priftin®, an antimycobacterial used for the treatment of active pulmonary TB has now been approved for LTBI, a new indication, to be used in combination with isoniazid (INH) in patients two years of age and older and at high risk of progression to TB disease.

The approval is based in part on the PREVENT TB study conducted by the CDC-Tuberculosis Trials Consortium (TBTC). The PREVENT TB study compared a 12-week, once-weekly regimen of Priftin® plus INH(3RPT/INH), using Direct Observation Therapy, with 9 months of self-administered daily INH (9INH). Tuberculosis disease developed in 5 of 3074 randomised patients in the 3RPT/INH group(cumulative rate, 0.16%) versus 10 of 3074 patients in 9INH group (cumulative rate, 0.32%), for a difference in cumulative rates of 0.17%, 95% CI (-0.43, 0.09). The proportion of patients completing treatment was 81.2 percent in the 3RPT/INH group and 68.3 percent in the 9INH group for a difference(3RPT/INH-9INH) of 12.8 percent, 95 percent CI (10.7, 15.0).

According to the WHO, tuberculosis is second only to HIV/AIDS as the greatest killer worldwide due to a single infectious agent. Approximately 9 million people fell ill with TB in 2013 and 1.5 million died from it. Sanofi, the company behind the drug, has been consistently involved in developing drugs for the management of TB. Since the late 1950s, the company has been involved in research and development efforts to treat, diagnose and prevent the disease.

“Today’s approval highlights the importance of public-private partnerships to address unmet public health challenges, with Sanofi working with the U.S. Centers for Disease Control to study new opportunities to treat latent TB infection,” said Paul Chew, M.D., Sanofi Global Chief Medical Officer. “The new approval for Priftin® exemplifies the commitment to treating TB upheld by Sanofi for more than a half century.”

As per the WHO’s *End TB strategy*, management of LTBI in people with a high risk of developing active TB is important for disease prevention and treatment.

Priftin® is currently only available in the US but Sanofi is exploring the potential for regulatory approvals in other countries as well.

Source: Sanofi

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