

Finafloxacin for the treatment of urinary tract infections

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Results from a double-blind phase 2 clinical study show that finafloxacin was a more effective and safe option than ciprofloxacin for the treatment of complicated urinary tract infections and acute pyelonephritis. This research is being presented at ASM's 55th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC/ICC).

Data from the study shows that patients treated with a five day course of finafloxacin had a higher, more rapid and more sustained level of pathogen eradication and improved clinical outcomes than those treated with the current standard of care, ciprofloxacin taken twice daily for 10 days. "Finafloxacin was found to be both safe and tolerable and could offer physician a viable additional option when treating bacterial infections in future," said David Dally, CEO of MerLion Pharmaceuticals Pte. Ltd.

225 adult Patients diagnosed with cUTI and acute pyelonephritis at 18 sites in Poland and Germany were randomized to receive 800 mg finafloxacin once daily either for a total of 5 or 10 days, or 400 mg (oral)/500 mg (iv) ciprofloxacin twice daily for 10 days. Physicians could switch from the initial intravenous to oral administration and release the patients from hospital after day 3.

Finafloxacin dosed for 5 days was as efficient as finafloxacin dosed for 10 days in a combined evaluation of the clinical and microbiological response with efficacy rates of 70% and 68% on day 17 of the study.



Both finafloxacin dosing regimens were more efficient than the treatment with ciprofloxacin for 10 days resulting in 57% efficacy. The short 5 day treatment period with finafloxacin did not result in an increased rate of relapses when compared to both 10 day treatment regimens in this study.

Furthermore, an interim evaluation on day 3 of the study revealed that finafloxacin eradicated pathogens more quickly than ciprofloxacin (89% vs. 79%). This rapid antibacterial activity of finafloxacin was not affected by urine pH, with comparable activity at acidic, neutral and basic conditions whereas ciprofloxacin eradicated pathogens less efficiently in patients with acidic urine.

"In contrast to ciprofloxacin, finafloxacin also showed a very rapid antimicrobial effect against <u>ciprofloxacin</u>-resistant pathogens and ESBL producing bacteria," said David Dally. Resistance to fluoroquinolones and ESBL producing bacteria that cause UTIs in particular are an increasing health problem.

Urinary tract infections (UTIs) are among the most prevalent infectious diseases in ambulatory and hospitalized populations, with a substantial financial burden on society, causing more than 7 million annual physician visits in the USA.

The results of this phase 2 clinical study were presented by MerLion Pharmaceuticals ("MerLion"), a biopharmaceutical company based in Singapore and Berlin.

Provided by American Society for Microbiology

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