UTI drug gepotidacin performs well in clinical trials compared to nitrofurantoin

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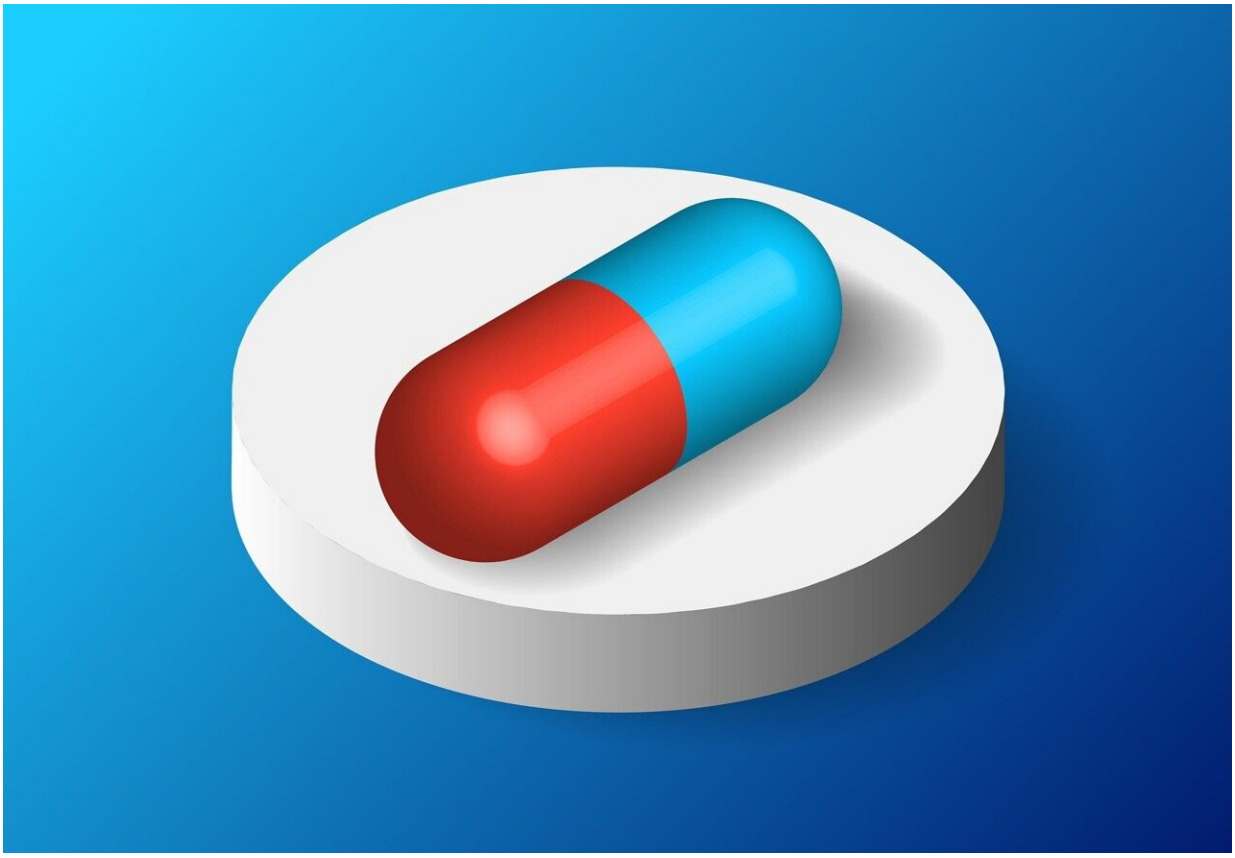

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A team of medical researchers with affiliations to British multinational pharmaceutical and biotechnology company GlaxoSmithKline (GSK) has found that a new antibiotic drug the company developed to treat

urinary tract infections (UTIs) performs well compared to nitrofurantoin in two clinical trials.

In their paper published in the journal *The Lancet*, the group describes aspects of two Phase III non-inferiority clinical studies run to test the efficacy and safety of the drug gepotidacin compared to nitrofurantoin. The editors at *The Lancet* have also published a Commentary piece in the same journal issue outlining the work by the team on this new effort.

Urinary tract infections are the most common bacterial infections in humans around the globe and are thus the most common target of antibacterial therapies. Prior research has shown that women are far more likely to contract such infections, and that more than half of women worldwide will suffer from at least one infection in their lifetime. However, bacteria are growing resistant, and researchers are seeking new drugs to safely treat patients with UTIs.

In this new effort, the team at GSK developed a drug called gepotidacin that has thus far been shown effective at treating patients with UTIs with few negative side effects. In this latest stage of development, the team tested their new drug in two Phase III non-inferiority clinical studies against the drug nitrofurantoin in preparation for making the drug available commercially.

The two clinical trials were called EAGLE-2 and EAGLE-3. Both involved testing gepotidacin, and both were double blind, double dummy trials for testing use in uncomplicated UTIs in women. The studies were done in parallel to compare results in two ways. In EAGLE-2, the emphasis was on learning more about differences in efficacy and safety based on age, whereas in EAGLE-3, the emphasis was on race.

The researchers found that gepotidacin was well tolerated by women of all ages and races—the most common negative side effect was mild

diarrhea. They also found a high success rate: 50.6% for EAGLE-2 and 58.5% for EAGLE-3. The efficacy of gepotidacin was non-inferior to nitrofurantoin in both trials, and was superior to it in EAGLE-3.

Gepotidacin was also effective against common and resistant uropathogens such as P. mirabilis, E. coli, and E. faecalis. The researchers conclude that gepotidacin is a potential new oral treatment for uncomplicated UTIs in women.

More information: Florian Wagenlehner et al, Oral gepotidacin versus nitrofurantoin in patients with uncomplicated urinary tract infection (EAGLE-2 and EAGLE-3): two randomised, controlled, double-blind, double-dummy, phase 3, non-inferiority trials, *The Lancet* (2024). DOI: 10.1016/S0140-6736(23)02196-7

Ased S M Ali et al, Gepotidacin, a new first-in-class antibiotic for treating uncomplicated urinary tract infection, *The Lancet* (2024). DOI: 10.1016/S0140-6736(23)02697-1