Blujepa (gepotidacin) – New drug approval

- On March 25, 2025, GSK announced the FDA approval of Blujepa (gepotidacin), for the **treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms with uncomplicated urinary tract infections (uUTI) caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii complex, Staphylococcus saprophyticus, and Enterococcus faecalis*.**

- The most common type of infection among women is uUTI. More than 50% of females experience a case of uUTI over their lifetime, and approximately 30% have recurrent episodes.

- Blujepa is a bactericidal, **first-in-class triazaacenaphthylene antibiotic** that inhibits bacterial Type II topoisomerases, DNA gyrase and topoisomerase IV, to inhibit DNA replication.

- The efficacy of Blujepa was established in two randomized , double-blind, double-dummy, non-inferiority studies of 1,201 female patients with nitrofurantoin-susceptible uUTI. Patients were randomized to Blujepa or nitrofurantoin. The primary endpoint was a composite of clinical cure and microbiological response on days 10 to 13 without use of other systemic antimicrobials.

    — Blujepa demonstrated non-inferiority to nitrofurantoin in both studies and superiority in one study, with reported treatment differences of 5.3 (95% CI: -2.4, 13.0) and 14.4 (95% CI: 6.4, 22.4).

- Warnings and precautions for Blujepa include dose- and concentration-dependent QTc prolongation, increased cholinergic effects, hypersensitivity reactions, *Clostridioides difficile* infections, and development of drug-resistant bacteria.

- The most common adverse reactions (≥ 1%) with Blujepa use were diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, and vulvovaginal candidiasis.

- The recommended dose of Blujepa is 1,500 mg (two 750 mg tablets) taken orally, twice daily (approximately 12 hours apart), for 5 days.

- GSK plans to launch Blujepa in the second half of 2025. Blujepa will be available as a 750 mg tablet.