

Novel Antibiotic Is Safe and Effective for Gonorrhea Treatment

Zoliflodacin worked as well as current standard treatment in a late-stage clinical trial.

November 7, 2023 By National Institute of Allergy and Infectious Diseases

NIH Statement on Preliminary Efficacy Results of First-in-Class Gonorrhea Antibiotic Developed Through Public-Private Partnership

A single dose of a novel oral antibiotic called zoliflodacin has been found to be as safe and effective as standard therapy for uncomplicated urogenital gonorrhea in an international Phase 3 non-inferiority clinical trial, according to the Global Antibiotic Research & Development Partnership (GARDP), the study sponsor.

Gonorrhea treatment options are increasingly limited due to antimicrobial resistance seen in *Neisseria gonorrhoeae*, the bacteria that cause gonococcal infection.

Because of the imperative to expand the gonococcal therapeutic pipeline, the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has contributed financial and scientific support to the development of zoliflodacin and applauds its non-governmental and private sector partners on successfully conducting the Phase 3 study. This research has generated important new evidence for a field in urgent need of alternative therapeutic options. Specifically, zoliflodacin may offer an alternative to current therapy for uncomplicated urogenital gonococcal infection.

“Decades-old antibiotics are becoming ineffective for treating *Neisseria gonorrhoeae*, which creates a huge global health burden. NIAID celebrates this exemplary public-private partnership for supporting science to improve the sexual health of people worldwide,” said NIAID Director Jeanne Marrazzo, MD. “These encouraging results should bolster additional, intersectoral efforts to develop safe and effective therapeutic options for gonorrhea and other bacteria that exhibit antimicrobial resistance.”

Gonorrhea, a common sexually transmitted infection, afflicts more than 80 million adults each year, according to the World Health Organization. While usually treatable with antibiotics, *N. gonorrhoeae* bacteria have demonstrated resistance to most existing classes of antibiotics, and strains have been detected that do not respond to the last remaining cephalosporin and macrolide options. Untreated gonorrhea can lead to serious and permanent health conditions, such as pelvic

inflammatory disease, painful swelling and blockages in male reproductive organs, and infertility.

Zoliflodacin is the first agent in the new spiropyrimidinetrione class of antibiotics that inhibit replication of bacterial DNA. The antibiotic is taken orally, as compared to the intramuscular injection required for current standard treatment. NIAID sponsored three clinical studies ([1](#), [2](#), [3](#)) to evaluate the safety, pharmacokinetics, and antimicrobial activity of zoliflodacin in volunteers, enabling research to progress to the Phase 3 trial reporting results today. GARDP conducted the current study with Inoviva Specialty Therapeutics, a subsidiary of Inoviva, Inc., based in Waltham, Mass. Full study results will be released through peer-reviewed channels and submitted to regulatory agencies as part of the information considered for licensure.

NIAID supports a comprehensive, multidisciplinary program of research on *N. gonorrhoeae* that includes basic research on pathogens, improved diagnostics, preventive vaccines, and additional alternative treatments. NIAID is grateful to the research sites and volunteers who participate in studies to improve the prevention and treatment of gonorrhea.

This [news release](#) was published by the National Institute of Allergy and Infectious Diseases on November 1, 2023.