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# FDA Approves Two New Treatments for Gonorrhea

Gepotidacin and zoliflodacin, two new types of antibiotics, can be used to treat gonorrhea that has developed resistance to current standard therapy.

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The Food and Drug Administration (FDA) this month approved two new oral medications for gonorrhea. These are the first new classes of antibiotics approved for the sexually transmitted infection in decades—and an urgent need, as gonorrhea is increasingly resistant to the drugs usually used to treat it.

On December 11, the FDA approved gepotidacin (Blujepa), from GSK, to treat uncomplicated urogenital gonorrhea in adolescents and adults with limited treatment options. The following day, the agency gave the green light to zoliflodacin (Nuzolvence), from Entasis Therapeutics, for the same indication.

“The availability of additional treatment options is of particular importance given the global rise in gonococcal drug resistance,” Peter Kim, MD, director of the FDA’s Center for Drug Evaluation and Research Division of Anti-infectives, said in a news release.

Gonorrhea is the second most common bacterial STI in the United States, after chlamydia. According to the latest surveillance report from the Centers for Disease Control and Prevention (CDC), gonorrhea cases declined by about 10% in 2024, but there were still more than half a million reported cases. Gonorrhea is more common among men than women and more so among gay and bisexual men compared with heterosexual men. While doxyPEP—taking a single dose of the antibiotic doxycycline soon after sex—substantially reduces the risk of acquiring chlamydia and syphilis, it is only modestly effective against gonorrhea.

Urogenital gonorrhea can cause painful urination and genital discharge, but many people, especially women, have no symptoms. Rectal and oropharyngeal (mouth and throat) infections may also occur. If left untreated, gonorrhea can lead to serious complications, including chronic pain and infertility. What’s more, it increases the likelihood of acquiring or transmitting HIV.

The CDC previously recommended a single injection of the antibiotic ceftriaxone plus the oral antibiotic azithromycin as standard treatment, but dropped azithromycin in 2020 due to growing drug resistance. Ceftriaxone resistance is also rising. There is currently no vaccine specifically for

gonorrhea, and a vaccine that prevents bacterial meningitis caused by related bacteria is at best marginally effective. Both gepotidacin and zoliflodacin were approved only for urogenital gonorrhea, not rectal or oropharyngeal infection, but experts expect they will be used off label for this purpose.

The approval of gepotidacin, the first-in-class triazaacenaphthylene antibiotic, is supported by results from the Phase III EAGLE-1 trial (NCT04010539), which enrolled more than 600 participants. They were randomly assigned to receive two 3,000 milligram doses of gepotidacin (each consisting of four 750 mg tablets) taken about 12 hours apart or standard treatment (a shot of ceftriaxone plus oral azithromycin).

As reported in The Lancet, the study showed that 93% of people who used gepotidacin were cured, as were 91% of those to used standard treatment. The most common side effects include diarrhea, nausea, vomiting, abdominal pain and flatulence, mostly mild or moderate. The Blujepa prescribing information includes warnings about heart rhythm abnormalities, hypersensitivity reactions and Clostridioides difficile infection. Gepotidacin was also approved earlier this year for uncomplicated urinary tract infections in women and adolescent girls.

The approval of zoliflodacin, the first spiropyrimidinetrione antibiotic, is based on a Phase III trial (NCT03959527) of more than 900 patients, 22% of whom were living with HIV. Initially discovered by AstraZeneca, the drug was developed by a private-public collaboration between Innoviva Specialty Therapeutics and the Global Antibiotic Research and Development Partnership, which should facilitate prompt access worldwide.

Study participants were randomized to receive a single 3-gram dose of zoliflodacin granules dissolved in water or standard treatment. According to another report in The Lancet, 91% of zoliflodacin recipients and 96% of those who received standard treatment were cured. The most common side effects include low white blood cell counts, headache, dizziness, nausea and diarrhea. The Nuzolvence prescribing information includes warnings about impaired fertility, pregnancy loss and fetal harm in animal studies, hypersensitivity reactions and Clostridioides difficile infection.

“The decades-long absence of new gonorrhea treatments, combined with rising global antibiotic resistance, has created significant challenges in managing this common but potentially serious sexually transmitted infection,” Edward Hook, MD, of the University of Alabama at Birmingham, who led the Nuzolvence trial, said in a news release. “A new antibiotic that does not require injection and can be used for patients who are allergic to penicillin or related drugs meets two important unmet needs in the treatment of gonorrhea.”

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