Stock-exchange announcement
For media and investors only

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Blujepa (gepotidacin) approved by US FDA as oral option for treatment of uncomplicated urogenital gonorrhea (uGC)

- ***Blujepa* is the first in a new antibiotic class for the treatment of gonorrhea approved in over three decades[1]**
- **Offers a new oral option for US patients with gonorrhea currently relying on injectable treatments**
- ***Neisseria gonorrhoeae* is a priority pathogen for the World Health Organization with significant need for new treatments[2]**

GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has approved a supplemental New Drug Application for gepotidacin as an oral option for adult and pediatric patients from 12 years of age weighing at least 45 kg who have limited or no alternative options for the treatment of uncomplicated urogenital gonorrhea caused by susceptible strains of *Neisseria gonorrhoeae* (e.g., where standard of care is contraindicated, or where patients are intolerant or unwilling to use first line treatment). This milestone follows the US FDA approval of gepotidacin earlier this year as an oral treatment for female adult and pediatric patients 12 years of age and older (weighing ≥40 kg) with uncomplicated urinary tract infection (uUTI).[3]

Gonorrhea is a common, sexually transmitted infection caused by *Neisseria gonorrhoeae*, which has been recognized by the World Health Organization as a priority pathogen[2] and an urgent public health threat by the US Centers for Disease Control and Prevention (CDC).[4] It affects both men and women and if left untreated or inadequately treated, it can lead to infertility and other sexual and reproductive health complications. In 2023, there were over 600,000 cases of gonorrhea reported in the United States according to the CDC, making it the second most commonly reported sexually transmitted infection in the country.[5] There is currently no licensed vaccine in the US for the prevention of gonorrhea infections and the standard treatment relies on an injectable antibiotic.[6]

Tony Wood, Chief Scientific Officer, GSK, said: “We’re proud to have delivered the first new class of antibiotics for gonorrhea in over three decades and a new oral option for US patients. The ability of *N. gonorrhoeae* to develop resistance to currently available options, including standard of care, makes it important to expand the range of effective oral treatments”.

The US application was based on positive results from the EAGLE-1 phase III trial which demonstrated that gepotidacin was non-inferior to standard of care combination treatment for gonorrhea (intramuscular ceftriaxone plus oral azithromycin). The trial also supported the safety and tolerability profile of gepotidacin, with no serious drug related adverse events observed in either the gepotidacin or the comparator arm. The most common reported adverse reactions were mild to moderate gastrointestinal events.[7]

With this approval, gepotidacin is now available to US patients for the treatment of uncomplicated urogenital gonorrhea when appropriate.

The development of gepotidacin has been funded in part with federal funds from the US Department of Health and Human Services, Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Other Transaction Agreement number HHSO100201300011C based on its

potential for use against secondary bacterial infections that may arise following chemical, biological, radiological, and nuclear (CBRN) incidents and with federal funds awarded by the US Department of Defense's Threat Reduction Agency under agreement number HDTRA1-07-9-0002.

About gepotidacin

Gepotidacin, discovered by GSK scientists, is a bactericidal, first-in-class triazaacenaphthylene antibiotic that inhibits bacterial DNA replication by a distinct binding site, a novel mechanism of action, and for most pathogens, provides well-balanced inhibition of two different Type II topoisomerase enzymes. This provides activity against *Neisseria gonorrhoeae* and most target uropathogens (such as *Escherichia coli* and *Staphylococcus saprophyticus*), including isolates resistant to current antibiotics. Due to this well-balanced inhibition for most pathogens, a single target-specific mutation may not significantly impact gepotidacin activity.

Please see full Prescribing Information including Medication Guide, available here.

About the EAGLE clinical program

The EAGLE-1 trial (NCT04010539) is part of a comprehensive global phase III clinical program for gepotidacin in adults and adolescents including:

EAGLE-1 (non-inferiority urogenital gonorrhea trial) enrolled approximately 600 patients with uncomplicated urogenital gonorrhea to compare the efficacy and safety of gepotidacin (oral, two doses of 3,000mg) to intramuscular ceftriaxone (500mg) plus oral azithromycin (1,000mg). The data were presented at the congress of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in April 2024[8] and published in *The Lancet* in April 2025.[7]

EAGLE-2 and EAGLE-3 (non-inferiority uUTI trials) enrolled approximately 3000 patients to compare the efficacy and safety of gepotidacin (1,500mg administered orally twice daily for five days) to nitrofurantoin (100mg administered orally twice daily for five days). The data were first presented at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in 2023[9] and published in *The Lancet* in February 2024.[10]

GSK in infectious diseases

GSK has pioneered innovation in infectious diseases for over 70 years, and the Company's pipeline of medicines and vaccines is one of the largest and most diverse in the industry, with a goal of developing preventive and therapeutic treatments for multiple disease areas or diseases with high unmet needs globally. Our expertise and capabilities in infectious disease strongly position us to help prevent disease and mitigate the challenge of antimicrobial resistance (AMR).

BLUJEPA (gepotidacin) tablets, for oral use

Indication(s) and Important Safety Information (ISI)

INDICATION

BLUJEPA is indicated for the treatment of the following infections caused by susceptible microorganisms:

- Uncomplicated urinary tract infections (uUTI) in female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg).
- Uncomplicated urogenital gonorrhea in adult and pediatric patients 12 years of age and older weighing at least 45 kg who have limited or no alternative treatment options. Approval of this indication is based on limited clinical safety data for this indication.

Usage to Reduce Development of Drug-Resistant Bacteria

To reduce the development of drug-resistant bacteria and maintain the effectiveness of BLUJEPA and other antibacterial drugs, BLUJEPA should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

BLUJEPA is contraindicated in patients with a history of severe hypersensitivity to BLUJEPA.

WARNINGS AND PRECAUTIONS

QTc Prolongation

- A dose and concentration-dependent prolongation of the QTc interval has been observed with BLUJEPA. Avoid use of BLUJEPA in patients with a history of QTc prolongation or with relevant pre-existing cardiac disease, patients taking antiarrhythmic agents, or in patients receiving drugs that prolong the QT interval.
- Due to an increase in gepotidacin exposure and the risk of QTc interval prolongation, avoid use of BLUJEPA in patients who have any of the following risk factors:
    - Concomitant use of strong CYP3A4 inhibitors
    - Severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min)
    - Severe hepatic impairment (Child-Pugh Class C).
- Additionally, avoid BLUJEPA in uncomplicated urogenital gonorrhea patients, who have any of the following risk factors for increased gepotidacin exposure.
    - Concomitant use of moderate CYP3A4 inhibitors
    - Two or more of the following risk factors: Body weight between 45 kg and 60 kg, Moderate renal impairment (eGFR 30 to 59 mL/min), Moderate hepatic impairment (Child-Pugh Class B)

Acetylcholinesterase Inhibition

- Dysarthria and other adverse reactions potentially attributed to acetylcholinesterase inhibition have been reported with BLUJEPA, a reversible acetylcholinesterase inhibitor. Increased cholinergic effects can be associated with severe adverse reactions, including atrioventricular block, bradycardia, bronchospasm, and seizures/convulsions. Monitor patients with medical conditions that may be exacerbated by acetylcholinesterase inhibition and patients receiving succinylcholine-type or non-depolarizing neuromuscular blocking agents, or systemic anticholinergic medications.

Hypersensitivity Reactions

- Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving BLUJEPA. If an allergic reaction to BLUJEPA occurs, discontinue the drug and institute appropriate supportive measures.

Clostridioides difficile Infection

- *Clostridioides difficile* infection (CDI) has been reported with nearly all systemic antibacterial agents, including BLUJEPA. Evaluate patients who develop diarrhea.

ADVERSE REACTIONS

- uUTI: The most common adverse reactions occurring in ≥1% of patients are diarrhea, nausea, abdominal pain, flatulence, headache, soft feces, dizziness, vomiting, and vulvovaginal candidiasis.

- Uncomplicated Urogenital Gonorrhea: The most common adverse reactions occurring in ≥2% of patients are diarrhea, nausea, abdominal pain, vomiting, flatulence, dizziness, soft feces, headache, fatigue, and hyperhidrosis

DRUG INTERACTIONS

- CYP3A4 Inhibitors: Increase gepotidacin exposure
  - Strong CYP3A4 inhibitors: Avoid concomitant use of BLUJEPA with strong CYP3A4 inhibitors
  - Moderate CYP3A4 inhibitors: In patients with uncomplicated urogenital gonorrhea, avoid concomitant use of BLUJEPA with moderate CYP3A4 inhibitors
- CYP3A4 Inducers: Decrease gepotidacin exposure
  - For uUTI: Avoid concomitant use of BLUJEPA with strong CYP3A4 inducers
  - For uncomplicated urogenital gonorrhea: Avoid concomitant use of BLUJEPA with strong and moderate CYP3A4 inducers.
- CYP3A4 Substrates: Avoid concomitant use of BLUJEPA with drugs that are extensively metabolized by CYP3A4 where minimal concentration changes may lead to serious adverse reactions.
- Digoxin: Due to an increase in digoxin exposures, consider monitoring digoxin serum concentration, as appropriate, with concomitant administration of BLUJEPA.

USE IN SPECIFIC POPULATIONS

- Renal Impairment: Avoid use of BLUJEPA in patients with severe renal impairment with eGFR <30 mL/min, including those receiving dialysis.
- Hepatic Impairment: Avoid use of BLUJEPA in patients with severe hepatic impairment (Child-Pugh Class C).

About GSK
GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

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[1] The last new class of antibiotics approved for the treatment of GC was the Fluoroquinolone class-Ciprofloxacin, with US approval in 1987 (CIPROFLOXACIN TABLETS, for oral use Initial U.S. Approval: 1987)
[2] WHO. Bacterial priority pathogens list, 2024: Bacterial pathogens of public health importance to guide research, development and strategies to prevent and control antimicrobial resistance. Available at: https://www.who.int/publications/i/item/9789240093461 Last accessed: November 2025
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[4] CDC. Antibiotic Resistance Threats Report. Available at: https://www.cdc.gov/antimicrobial-resistance/media/pdfs/covid19-impact-report-508.pdf Last accessed: August 2025
[5] CDC. National Overview of STIs in 2023. Available at: https://www.cdc.gov/sti-statistics/annual/. Last accessed: November 2025
[6] CDC. STI treatment guideline. Available: https://www.cdc.gov/std/treatment-guidelines/default.htm Last accessed: November 2025
[7] Ross J, et al, "Oral gepotidacin for the treatment of uncomplicated urogenital gonorrhoea (EAGLE-1): a phase 3 randomised, open-label, non-inferiority, multicentre study" in *The Lancet*, 2025; 05:1608-20; https://doi.org/10.1016/ S0140-6736(25)00628-2
[8] GSK. EAGLE 1 phase III data show potential for gepotidacin as a new oral treatment option for uncomplicated urogenital gonorrhoea (GC) amid growing resistance to existing treatments. Available at: https://www.gsk.com/en-gb/media/press-releases/eagle-1-phase-iii-data-show-potential-for-gepotidacin-as-a-new-oral-treatment-option-for-uncomplicated-gc/ Last accessed: November 2025.
[9] GSK. Gepotidacin's positive phase III data shows potential to be the first in a new class of oral antibiotics for uncomplicated urinary tract infections in over 20 years. Available at: https://www.gsk.com/en-gb/media/press-releases/gepotidacin-s-positive-phase-iii-data-shows-potential-to-be-the-first-in-a-new-class-of-oral-antibiotics-for-uncomplicated-urinary-tract-infections/ Last accessed: November 2025.
[10] F.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" in *The Lancet*, vol. 403, Issue 10428, 741-755, Feb 2024.