Stock-exchange announcement

For media and investors only

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Gepotidacin accepted for priority review by the US FDA for the oral treatment of uncomplicated urogenital gonorrhea

- Submission supported by positive phase III data in patients with uncomplicated urogenital gonorrhea in EAGLE 1 trial[1]
- Significant need for new antibiotics for gonorrhea, a priority pathogen for the World Health Organization[2]
- If approved, gepotidacin would offer a new oral option to US patients currently relying on injectable treatments
- December 11, 2025 assigned as Prescription Drug User Fee Act (PDUFA) goal date for FDA decision

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GSK plc (LSE/NYSE: GSK) today announced that the US Food and Drug Administration (FDA) has accepted for priority review a supplemental New Drug Application for gepotidacin as an oral option for the treatment of uncomplicated urogenital gonorrhea in patients 12 years of age and older (weighing ≥45 kg). The US FDA has assigned a Prescription Drug User Fee Act action date of December 11, 2025. In March 2025, gepotidacin was approved by the US FDA under the licensing name *Blujepa* (1,500mg administered orally twice daily for five days) as 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. There were more than 600,000 cases of gonorrhea reported in the United States in 2023 according to the CDC, making it the second most commonly reported sexually transmitted infection in the country.[5] There is currently no vaccine licensed in the US for the prevention of gonorrhea infection and the standard of care is injectable treatment which may not be suitable or available for all patients.[6]

The US application is based on results from the EAGLE-1 phase III trial recently published in *The Lancet*, showing that gepotidacin (oral, two doses of 3,000mg) was non-inferior, with 92.6% (187/202, [95% CI 88·0 to 95·8]) success rates at urogenital site when compared to 91.2% (186/204, [95% CI 86.4-94.7]) success rates for intramuscular ceftriaxone (500mg) plus oral azithromycin (1,000mg) combined therapy, a leading combination treatment regimen for gonorrhea. Additionally, there were no failures at the urogenital site due to bacterial persistence of *N. gonorrhoeae* in either treatment arm. The safety and tolerability profile of gepotidacin in the EAGLE-1 trial was consistent with results seen in previous clinical trials, with no serious drug related adverse events observed in either the gepotidacin or the comparator arm. The most common reported adverse reactions were mild (45% Grade 1) to moderate (29% Grade 2) gastrointestinal events.[1]

This is the second major indication filed in the US for gepotidacin, and review of regulatory submissions for the uUTI indication is also ongoing in the UK and Australia.

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 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) compared the efficacy and safety of gepotidacin (oral, two doses of 3,000mg) to intramuscular ceftriaxone (500mg) plus oral azithromycin (1,000mg) in approximately 600 patients with uncomplicated urogenital gonorrhea. The data were presented at ESCMID in April 2024[7] and published in *The Lancet* in April 2025.[1]

EAGLE-2 and EAGLE-3 (non-inferiority uUTI trials) compared 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 European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in 2023.[8]

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 female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg) with uncomplicated urinary tract infections (uUTI) caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Citrobacter freundii* complex*, Staphylococcus saprophyticus,* and *Enterococcus faecalis.*

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, and in patients receiving drugs that prolong the QT interval. Due to an increase in BLUJEPA exposure, avoid concomitant administration of BLUJEPA with strong CYP3A4 inhibitors, in patients with severe hepatic impairment (Child-Pugh Class C), and in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min)

Acetylcholinesterase inhibition

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

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-Associated Diarrhea

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

ADVERSE REACTIONS

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

DRUG INTERACTIONS

CYP3A4 Inhibitors: Avoid coadministration of BLUJEPA with strong CYP3A4 inhibitors due to increased gepotidacin exposure

CYP3A4 Inducers: Avoid coadministration of BLUJEPA with strong CYP3A4 inducers due to decreased gepotidacin exposure

CYP3A4 Substrates: Avoid coadministration of BLUJEPA with drugs that are extensively metabolized by CYP3A4 and have a narrow therapeutic window

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.

GSK inquiries

Media:	Simon Moore	+44 (0) 20 8047 5502	(London)
	Simon Steel	+44 (0) 20 8047 5502	(London)
	Kathleen Quinn	+1 202 603 5003	(Washington DC)
	Alison Hunt	+1 540 742 3391	(Washington DC)
Investor Relations:	Constantin Fest	+44 (0) 7831 826525	(London)
	James Dodwell	+44 (0) 20 8047 2406	(London)
	Mick Readey	+44 (0) 7990 339653	(London)
	Steph Mountifield	+44 (0) 7796 707505	(London)
	Jeff McLaughlin	+1 215 751 7002	(Philadelphia)
	Frannie DeFranco	+1 215 751 3126	(Philadelphia)

Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2024, and GSK's Q2 Results for 2025.

Registered in England & Wales:
No. 3888792

Registered Office:
79 New Oxford Street
London
WC1A 1DG

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