

# 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 gonorrhoea (uGC)**

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

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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 paediatric patients from 12 years of age weighing at least 45 kg who have limited or no alternative options for the treatment of uncomplicated urogenital gonorrhoea 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 paediatric patients 12 years of age and older (weighing ≥40 kg) with uncomplicated urinary tract infection (uUTI).<sup>3</sup>

Gonorrhoea is a common, sexually transmitted infection caused by *Neisseria gonorrhoeae*, which has been recognised by the World Health Organization as a priority pathogen<sup>2</sup> and an urgent public health threat by the US Centers for Disease Control and Prevention (CDC).<sup>4</sup> 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 gonorrhoea reported in the United States according to the CDC, making it the second most commonly reported sexually transmitted infection in the country.<sup>5</sup> There is currently no licensed vaccine in the US for the prevention of gonorrhoea infections and the standard treatment relies on an injectable antibiotic.<sup>6</sup>

**Tony Wood, Chief Scientific Officer, GSK**, said: “We’re proud to have delivered the first new class of antibiotics for gonorrhoea 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 gonorrhoea (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.<sup>7</sup>

With this approval, gepotidacin is now available to US patients for the treatment of uncomplicated urogenital gonorrhoea 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

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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.

The updated US Prescribing Information will be available [here](#).

## About the EAGLE clinical programme

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

EAGLE-1 (non-inferiority urogenital gonorrhoea trial) enrolled approximately 600 patients with uncomplicated urogenital gonorrhoea 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<sup>8</sup> and published in *The Lancet* in April 2025.<sup>7</sup>

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<sup>9</sup> and published in *The Lancet* in February 2024.<sup>10</sup>

## 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).

## 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](https://www.gsk.com).

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### 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 Q3 Results for 2025.

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<sup>1</sup> 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](#))

<sup>2</sup> 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

<sup>3</sup> GSK. *Blujepa* approved by US FDA for treatment of uncomplicated urinary tract infections. Available at: <https://www.gsk.com/en-gb/media/press-releases/blujepa-gepotidacin-approved-by-us-fda-for-treatment-of-uncomplicated-urinary-tract-infections/> Last accessed: November 2025

<sup>4</sup> CDC. Antibiotic Resistance Threats Report. Available at: <https://www.cdc.gov/antimicrobial-resistance/media/pdfs/covid19-impact-report-508.pdf> Last accessed: August 2025

<sup>5</sup> CDC. National Overview of STIs in 2023. Available at: <https://www.cdc.gov/sti-statistics/annual/>. Last accessed: November 2025

<sup>6</sup> CDC. STI treatment guideline. Available: <https://www.cdc.gov/std/treatment-guidelines/default.htm> Last accessed: November 2025

<sup>7</sup> 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](https://doi.org/10.1016/S0140-6736(25)00628-2)

<sup>8</sup> 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.

<sup>9</sup> 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.

<sup>10</sup> Wagenlehner F. 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.